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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
PITTSBURGH DIVISION

Sara Bloch, Mary Cease, and the Housing Authority of Indiana County, *Plaintiffs*, v. U.S. Department of Housing and Urban Development and Marcia Fudge, in her official capacity as Secretary, U.S. Department of Housing and Urban Development, *Defendants*.	:	Case No. 2:23-cv-01660-NR

PLAINTIFFS'
FIRST AMENDED COMPLAINT

INTRODUCTION

1. This lawsuit concerns Hobbesian choices faced by the plaintiffs: for Sarah Bloch and Mary Cease – two low-income Pennsylvanians in need of federal housing assistance that lawfully use medical marijuana under Pennsylvania state law – receive federal assistance for safe and secure housing *or* their life-changing medicine; for the Housing Authority of Indiana County ("HAIC") – the Pennsylvania entity responsible for administering federal housing assistance to low-income Pennsylvanian's – comply with a Pennsylvania court order *or* lose all federal funding.

2. Since 1970, marijuana and its psychoactive ingredient, tetrahydrocannabinol ("THC"), have been listed as Schedule I substances under the Controlled Substances Act, 21 U.S.C. §§801, *et seq*. ("CSA"), rendering it illegal to manufacture, distribute, dispense, or possess marijuana.

3. Under the CSA, as enacted in 1970, a Schedule I substance: (i) has a high potential for abuse, (ii) has no accepted medical use, and (iii) cannot be used safely even under medical supervision.

4. However, much has changed since the CSA was passed over 50 years ago. Today, 44 states plus the District of Columbia and certain U.S. Territories have legalized medical marijuana and 22 states have legalized it for adult use. In fact,

only 4 states in the entire United States continue to criminalize any and all use of marijuana.

5. Over the past 15 years, the federal government's treatment of people and entities that produce or use marijuana has also evolved:

a. Since at least 2009, the U.S. Department of Justice ("DOJ") has issued written policies on limiting its enforcement of federal drug laws relating to the production and use of medical marijuana so long as such production and use was pursuant to and under the supervision of a state's marijuana laws and regulatory agencies;

b. In 2012, the United States Department of Agriculture ("USDA"), the agency tasked with overseeing the Supplemental Nutrition Assistance Program ("SNAP"), issued a policy memo indicating that while medical marijuana expenditures could not count towards allowable medical deductions medical marijuana users were not disqualified from the SNAP assistance program;

c. For the first time in 2014, Congress used the power of the purse via the commonly known Rohrbacher-Farr Amendment to restrain the DOJ from investigating or prosecuting any medical marijuana operations so long as such operations were compliant under the laws of the state tasked with overseeing and regulating them. The

Rohrbacher-Farr Amendment has been extended or re-authorized without fail since its initial passage;

d. In 2015, the then U.S. Surgeon General Vivek Murthy stated in an interview that marijuana can be helpful in treating certain medical conditions and symptoms;

e. In June 2018, the U.S. Food and Drug Administration ("FDA") approved Epidiolex, a pharmaceutical-grade, marijuana-based cannabidiol ("CBD") extract, to treat children suffering from Dravet and Lennox-Gastaut Syndromes;

f. The FDA has also approved other THC-based medications such as dronabinol and nabilone for the treatment of nausea in patients undergoing cancer chemotherapy and to stimulate appetites in patients with AIDS or wasting syndrome (these are the same medical conditions commonly approved by states to be treated with medical marijuana);

g. The U.S. Drug Enforcement Administration ("DEA") reports that "[n]o death from overdose of marijuana has been reported." A copy of the DEA "Drug Fact Sheet" is attached hereto as **Exhibit 1**;

h. In a 2018 research article, the National Institute of Health ("NIH") concluded that the "compelling nature of these data and the relative

safety profile of cannabis warrant further exploration of cannabis as an adjunct or alternative treatment to [opioid use disorder]";

i. In 2022, President Biden was the first president to propose incorporating the Rohrbacher-Farr amendment into the national budget;

j. On July 28, 2023, the Department of Veterans Affairs ("VA") issued VHA Directive 1315 that provides: "Veterans must not be denied [Veterans Health Administration] services solely because they are participating in a State-approved marijuana program or because they acknowledge use of marijuana."

k. On August 29, 2023, the United States Department of Health and Human Services ("DHHS"), based on a report authored by the FDA, recommended to the DEA that marijuana be rescheduled under the CSA from a Schedule I substance to a Schedule III substance.

6. The federal government's actions over the past 15 years with respect to marijuana that culminated in DHHS's recommendation that it be re-classified as a Schedule III substance indicates the federal government's recognition that marijuana is no longer considered among the most dangerous substances and can be an effective medical treatment especially when supervised under a state medical program.

7. Despite evolving lenience afforded medical marijuana patients from the USDA, FDA, VA and DHHS, the U.S. Department of Housing and Urban Development ("HUD") continues to apply marijuana's Schedule I status robotically, uncompromisingly, and cruelly under the CSA which acts to deprive low-income individuals who are suffering from debilitating medical conditions and lawfully treating these conditions with medical marijuana under state law from receiving federal housing assistance.

8. Plaintiffs seek a declaratory order and related injunctive relief that the Quality Housing and Work Responsibility Act, 42 U.S.C. §§13661-13664 ("QHWRA"), the federal law governing eligibility for Section 8 federal housing assistance, does not require HUD or the local housing authority that administers the Section 8 program to prohibit admission to applicants that are lawfully using marijuana under state supervised programs.

9. In Pennsylvania, state courts have already held that QHWRA does not prohibit and actually requires housing authorities to establish standards to determine the eligibility of a Section 8 applicant who is lawfully using medical cannabis under Pennsylvania law. *Cease v. Housing Auth. Indiana Cnty*., 247 A.3d 57 (Pa. Cmwlth. 2021), *pet. for allocatur denied*, 263 A.3d 243 (Pa. 2021). Plaintiffs seek a declaratory order and related injunctive relief that, in Pennsylvania, HUD is

obligated to respect the *Cease* decision and cannot threaten to withhold funding from HAIC for its compliance with said decision.

10. Given that the various branches of government as well as a wide-swath of federal agencies have treated state-compliant medical marijuana entities with leniency and forgiveness, Plaintiffs further seek a declaratory order and related injunctive relief that HUD's continued application of QHWRA and the CSA so as to prohibit Section 8 applicants that use medical marijuana in compliance with a state-regulated medical marijuana program unconstitutionally discriminates, without any rational basis, against low-income and disabled individuals.

11. Additionally, Plaintiffs seek a declaration that HUD is estopped from re-litigating the same issues presented and ruled upon in a previous decision whereby HUD's interests were adequately represented by the HAIC, and in so doing grant permanent injunctive relief to prevent HUD from de-funding the HAIC for said reasons.

12. Finally, plaintiffs seek a declaratory order and related injunctive relief that plaintiff HAIC is required under Pennsylvania law to afford Section 8 applicants, lawfully using medical marijuana pursuant to Pennsylvania Medical Marijuana Act, 35 P.S. §10231.101, *et seq*. ("MMJ Act") housing and that HAIC's funding cannot be stripped away in punishment for said compliance.

13. This lawsuit ***does not*** intend or seek to re-classify, re-schedule, or de-schedule marijuana under the CSA. If Plaintiffs prevail on one or more of its claims, plaintiffs recognize and acknowledge that marijuana would still be considered a Schedule I substance if or until either (i) Congress acts to change its classification or (ii) the United States Attorney General re-classifies marijuana under the CSA.

PROCEDURAL HISTORY

14. In *Cease*, Pennsylvania courts have already ruled that, under the MMJ Act, a Section 8 housing applicant's admission cannot be prohibited if the applicant is lawfully using medical marijuana. Instead, the HAIC – the local entity that administers the federal funding disbursed by HUD for the Section 8 housing program and was a party to the *Cease* decision – was required to "establish fair and reasonable standards for determining in what circumstances admission to Section 8 housing is prohibited for an applicant who is legally using medical marijuana under state law" and was ordered to apply those standards to plaintiff Mary Cease's case. *Cease*, 247 A.3d at 65. A copy of the *Cease* decision is attached hereto as **Exhibit 2**.

15. During and subsequent to the *Cease* decision, HUD made it clear to Plaintiff HAIC, the appellee housing authority in the *Cease* case, that compliance with the Commonwealth Court's decision would result in the withholding of all federal funds to the HAIC, the primary source of the HAIC's funding.

16. As a result of HUD's disregard of the *Cease* decision and its threats to withhold federal funds from the HAIC, the HAIC is left to choose between complying with HUD's requirements and continuing to deny lawful medical marijuana patients with housing so that the HAIC may maintain funding, or providing low income medical marijuana patients with much needed housing pursuant to a valid court order.

17. Complying with HUD's requirements will violate an Order of the Pennsylvania Commonwealth Court, will result in a finding of contempt, will subject HAIC to significant monetary penalties for being in contempt of a court order and will result in continuous and costly litigation every time a medical marijuana patient is denied housing *pursuant to HUD guidelines on medical marijuana usage* (while low-income patients remain unhoused).

18. Admitting medical marijuana patients, who are otherwise eligible except for HUD's prohibition of medical marijuana, into Section 8 housing risks HUD following through with their threat to withhold funding, which jeopardizes the housing status of not only Cease and Bloch, but also every tenant of Section 8 housing in Indiana County, Pennsylvania.

19. Accordingly, plaintiffs bring this lawsuit to end HUD's disparate treatment of the most vulnerable in our population and to seek declarations that federalism mandates HUD respect the *Cease* decision, that applicable federal law

does not require an applicant's denial to a Section 8 housing program, and that under Pennsylvania state law, Section 8 Housing Program applicants legally using medical marijuana are entitled to reasonable accommodations; additionally, plaintiffs seek permanent injunctive relief to prevent HUD from withholding federal funds on the basis of the HAIC's compliance with state law.

JURISDICTION

20. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §1331 (federal question) and 28 U.S.C. §1343 (civil rights actions) as this case concerns a violation of the United States Constitution and various federal laws.

21. Venue is properly vested in the District Court for the Western District of Pennsylvania pursuant to 28 U.S.C. §1391(e) because defendant HUD is a federal agency and defendant Fudge is an officer of the United States acting in her official capacity, and because a substantial part of the events or omissions giving rise to the claims occurred within the court's jurisdiction.

22. This Court can grant declaratory and injunctive relief under 28 U.S.C. §2201 (declaratory judgment) and 28 U.S.C §2202 (injunctive relief) for violations of the Fifth Amendment to the U.S. Constitution and various federal laws. This Court also has jurisdiction to hear any state claims related to the same set of facts underpinning Plaintiffs' federal claims. 28 U.S.C. §1367.

PARTIES

23. Plaintiff Sara Bloch is a single parent, low-income, disabled Pennsylvania resident who was denied admission into the HAIC-administered Section 8 Housing Program based solely on her voluntary disclosure to the HAIC that she lawfully used medical marijuana under Pennsylvania's MMJ Act.

24. Plaintiff Mary Cease is a veteran, domestic abuse survivor, certified-disabled, and low-income Pennsylvania resident who, in 2018, sought admission into the HAIC-administered Section 8 Housing Program but was denied admittance based solely on her voluntary disclosure to the HAIC that she lawfully used medical marijuana under the MMJ Act. Ms. Cease was the named appellant in the *Cease* case.

25. Plaintiff HAIC is a duly Pennsylvania registered residential finance authority created pursuant to the Pennsylvania Housing Authorities Law, 35 P.S. §1544, and is the entity responsible for administering all federal Section 8 housing funding for Indiana County, Pennsylvania. The HAIC was the named appellee in the *Cease* case, and, pursuant to said decision, is required to "establish fair and reasonable standards for determining in what circumstances admission to Section 8 housing is prohibited for an applicant who is legally using medical marijuana under state law" but the HAIC has failed to do so because of defendant HUD's threats to cut off all federal funding for Indiana County's Section 8 Housing Program.

26. Defendant HUD is an executive federal agency that is purportedly "focused on housing and community development and dedicated to equity, inclusive communities, and quality, affordable homes for all." As part of its first strategic goal, HUD allegedly seeks to "[f]ortify support for vulnerable populations, underserved communities, and Fair Housing enforcement." As part of its second strategic goal, HUD allegedly seeks to "[i]mprove rental assistance to address the need for affordable housing."[1] Part of HUD's responsibilities include managing and disbursing to housing authorities congressional appropriations for low-income housing, including the funding for what is commonly referred to as the Section 8 housing program. HUD's mission statement includes the goal of building "communities free from discrimination."[2]

27. Defendant Marcia Fudge was appointed by President Biden in 2021 to serve as the Secretary of HUD and in that role Secretary Fudge leads, manages, and otherwise oversees the establishment and implementation of HUD policies and programs.

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[1] FY 2022-2026 HUD Strategic Plan, www.hud.gov/HUD-FY22-26-Strategic-Plan-Focus-Areas (last accessed Jan. 8, 2024).

[2] Available at https://www.hud.gov/program_offices/cfo/afr/section1#:~:text=The%20core%20focus%20of%20HUD's,communities%20free%20from%20discrimination%3B% (Last accessed Jan. 8, 2024).

28. Through a January 31, 2022 letter from her Deputy Assistant Secretary, Danielle Bastarache, Secretary Fudge reiterated her position to deny housing to new applicants who legally use medical marijuana under state law. A copy of the January 31, 2022 letter is attached hereto as **Exhibit 3**.

FACTUAL BACKGROUND

The Section 8 Housing Program

29. "It is the policy of the United States … to assist States and political subdivisions of States to remedy the unsafe housing conditions and the acute shortage of decent and safe dwellings for low-income families [and] … to address the shortage of housing affordable to low-income families." 42 U.S.C. §1437(a)(1)(A)-(B).

30. In passing QHWRA it was the intent of Congress to vest in "public housing agencies the maximum feasible authority, discretion, and control" and to deregulat[e] and decontrol[] public housing agencies" in order to make the Section 8 housing program more successful. 42 U.S.C. §1437(a)(1)(C).

31. Today, the largest federal housing assistance program is the Housing Choice Voucher program, commonly referred to as "Section 8" housing. *See* 42

U.S.C. §1437f(o).[3] This Program is federally administered by HUD with each state being responsible for its implementation.

32. Admission into the Section 8 housing program is open only to citizens and certain non-citizen families who are income-eligible under HUD's regulations. 24 C.F.R. §982.201(a).

33. To satisfy the income eligibility requirement for admission into the Section 8 housing program a family must qualify as being a "very low" or "extremely low" income family. 24 C.F.R. §982.201(b).

34. For purposes of the Section 8 housing program, the term "very low-income family" is defined as a family whose annual income does not exceed 50% of the median income for the area. 24 C.F.R. §5.603.

35. HUD's definition of "very low-income families" is defined as follows:

> A family whose annual income does not exceed 50 percent of the median family income for the area, as determined by HUD with adjustments for smaller and larger families, except that HUD may establish income ceilings higher or lower than 50 percent of the median income for the area if HUD finds that such variations are necessary because of unusually high or low family incomes.

Id.

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[3] Roger Valdez, *Series: A Brief History of the Section 8 Housing Voucher Program*, www.FORBES.com available at https://www.forbes.com/sites/rogervaldez/2023/02/09/series-a-brief-history-of-the-section-8-housing-voucher-program/?sh=257202db511f (last accessed Jan. 8, 2024).

36. For purposes of the Section 8 housing program, the term "extremely low-income family" is defined as a family whose annual income does not exceed the higher of the poverty limit applicable to the family's size or 30% of the median income for the area. *Id.*

37. HUD's definition of "extremely low-income families" is defined as follows,

> A very low-income family whose annual income does not exceed the higher of:
>
> (1) The poverty guidelines established by the Department of Health and Human Services applicable to the family of the size involved (except in the case of families living in Puerto Rico or any other territory or possession of the United States); or
>
> (2) Thirty (30) percent of the median income for the area, as determined by HUD, with adjustments for smaller and larger families, except that HUD may establish income ceilings higher or lower than 30 percent of the area median income for the area if HUD finds that such variations are necessary because of unusually high or low family incomes.

Id.

38. To qualify as a "very low-income family" or an "extremely low-income family" in Pennsylvania, under HUD guidelines, a family must meet the following income eligibility criteria:

Very Low-Income Limit (VLIL) 50% of Median*							
1 Person	2 Person	3 Person	4 Person	5 Person	6 Person	7 Person	8 Person
$33,400	$38,150	$42,900	$47,700	$51,500	$55,350	$59,150	$62,950

Extremely Low-Income Limit (ELIL) 30% of Median*							
1 Person	2 Person	3 Person	4 Person	5 Person	6 Person	7 Person	8 Person
$20,050	$22,900	$25,750	$28,650	$30,900	$33,200	$35,500	$37,800

See HUD's FY 2023 Income Limits Documentation System, Pennsylvania State Income Limits.[4]

39. To qualify as a "very low-income family" or an "extremely low-income family" in Indiana County, Pennsylvania, under HUD guidelines, a family must meet the following income eligibility criteria:

[4] Available at https://www.huduser.gov/portal/datasets/il/il2023/2023summary.odn?inputname=STTLT*4299999999%2BPennsylvania&selection_type=county&stname=Pennsylvania&statefp=42.0&year=2023 (last accessed Jan. 8, 2024).

FY 2023 Income Limit Category	Persons in Family							
	1	2	3	4	5	6	7	8
Very Low (50%) Income Limits ($) Click for More Detail	27,250	31,150	35,050	**38,900**	42,050	45,150	48,250	51,350
Extremely Low Income Limits ($)* Click for More Detail	16,350	19,720	24,860	**30,000**	35,140	40,280	45,420	50,560
Low (80%) Income Limits ($) Click for More Detail	43,550	49,800	56,000	**62,200**	67,200	72,200	77,150	82,150

See HUD's FY 2023 Income Limits Documentation System, Indiana County, Pennsylvania Income Limits.[5]

40. In addition to the income eligibility component, Section 8 applicants must comply with QHWRA, 42 U.S.C. §§13661-13664, insofar as it sets forth applicant screening and tenancy termination requirements related to safety and security in public and federally assisted housing programs.

41. Section 13661(b)(1)(A) of QHWRA (Screening of applicants for federally assisted housing) provides:

[5] Available at https://www.huduser.gov/portal/datasets/il/il2023/2023summary.odn?STATES=42.0&INPUTNAME=NCNTY42063N42063*4206399999%2BIndiana+County&statelist=&stname=Pennsylvania&wherefrom=%24wherefrom%24&statefp=42&year=2023&ne_flag=&selection_type=county&incpath=%24incpath%24&data=2023&SubmitButton=View+County+Calculations (last accessed Jan. 8, 2024).

> **(b) INELIGIBILITY OF ILLEGAL DRUG USERS AND ALCOHOL ABUSERS**
>
> **(1) IN GENERAL**
>
> Notwithstanding any other provision of law, a public housing agency or an owner of federally assisted housing, as determined by the Secretary, shall establish standards that prohibit admission to the program or admission to federally assisted housing for any household with a member—
>
> (A) who the public housing agency or owner determines is *illegally using* a controlled substance …

42 U.S.C. §13661(b)(1)(A) (emphasis added).

42. Section 13662(a)(1) of QHWRA (Termination of tenancy and assistance for illegal drug users and alcohol abusers in federally assisted housing) provides:

> **(a) IN GENERAL**
>
> Notwithstanding any other provision of law, a public housing agency or an owner of federally assisted housing (as applicable), shall establish standards or lease provisions for continued assistance or occupancy in federally assisted housing that allow the agency or owner (as applicable) to terminate the tenancy or assistance for any household with a member—
>
> (1) who the public housing agency or owner determines is *illegally using* a controlled substance …

42 U.S.C. §13662(a)(1) (emphasis added).

43. QHWRA does not disqualify applicants for their use of a controlled substance; rather, QHWRA only disqualifies Section 8 housing applicants if they "illegally" use a controlled substance.

Current Federal and State Treatment of Marijuana

44. In 1970, the U.S. Congress signed into law the CSA, 21 U.S.C. §§801, *et seq*., wherein it scheduled "marihuana" as a Schedule I drug where a drug on Schedule I was defined as having a high potential for abuse, no currently accepted medical use, and a lack of accepted safety for its use under medical supervision. 21 U.S.C. §812(b)-(c).

45. Today, marijuana and tetrahydrocannabinols (e.g., Delta-9 tetrahydrocannabinol or THC) remain Schedule I substances under the CSA.

46. Other drugs listed on Schedule I of the CSA include heroin, Lysergic Acid Diethylamide (LSD), and ecstasy.

47. Pursuant to the Tenth Amendment of the U.S. Constitution and in contravention of the CSA, California in 1996, was the first state to decriminalize and legalize marijuana for medicinal purposes.

48. On April 21, 1999, the DHHS filed for a U.S. Patent on "Cannabinoids As Antioxidants and Neuroprotectants" wherein the patent application states, in part, "[c]annabinoids have been found to have antioxidant properties … [t]his new found property makes cannabinoids useful in the treatment and prophylaxis of wide variety of oxidation associated diseases, such as ischemic, age-related inflammatory and autoimmune diseases." A copy of the patent application approval is attached hereto as **Exhibit 4**. On October 7, 2003, the United States Patent and Trademark Office

("USPTO") issued a patent, Patent No. US 6,630,507 wherein the USPTO, a function of the federal government, determined that marijuana possesses medical health benefits.

49. "Cannabinoids" are a class of biological compounds most frequently sourced from and associated with cannabis plants, the scientific term for marijuana, and create a medical benefit by binding to cannabinoid receptors found in the human brain.[6] The most common cannabinoids are THC and CBD.

50. By 2009, thirteen states – California, Alaska, Nevada, Oregon, Washington, Maine, Colorado, Hawaii, Montana, Vermont, Rhode Island, New Mexico, and Michigan – had legalized marijuana at the state level for medical use.

51. Despite marijuana still being considered a Schedule I substance, on October 19, 2009, U.S. Deputy Attorney General David W. Ogden of the DOJ issued a memorandum ("Ogden Memo") to United States Attorneys providing, in part:

> As a general matter, pursuit of these priorities should not focus federal resources in your States on individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana. For example, prosecution of individuals with cancer or other serious illnesses who use marijuana as part of a recommended treatment regimen consistent with applicable state law, or those caregivers in clear and

[6] Natl. Health Institute, *National Library of Medicine: Cannabinoids*, last updated Feb. 27, 2023 available at https://www.ncbi.nlm.nih.gov/books/NBK556062/#:~:text=Cannabinoids%2C%20broadly%20speaking%2C%20are%20a,Cannabis%20indica%2C%20and%20Cannabis%20ruderalis. (last visited Jan. 8, 2024).

> unambiguous compliance with existing state law who provide such individuals with marijuana, is unlikely to be an efficient use of limited federal resources. On the other hand, prosecution of commercial enterprises that unlawfully market and sell marijuana for profit continues to be an enforcement priority of the Department.

Ogden Memo at 1-2; a copy of the Ogden Memo is attached hereto as **Exhibit 5**.

52. Between 2009 and 2013, an additional seven states – Arizona, New Jersey, Delaware, Connecticut, Massachusetts, Illinois, Maryland, and New Hampshire – and the District of Columbia enacted state laws that legalized medical marijuana for certain residents within their state's respective jurisdictions.

53. On July 10, 2012, the USDA issued a memo, "Medical Deductions—Medical Marijuana and Other Illegal Substances", that instructed that medical marijuana costs may not be deducted as "allowable medical expenses" in calculating a household's eligibility to receive federal Supplemental Nutrition Assistance Program (SNAP) benefits; but said memo did not disqualify households from receiving SNAP benefits because of medical marijuana usage. A copy of the memo is attached hereto as **Exhibit 6**.

54. On August 29, 2013, U.S. Deputy Attorney General James M. Cole of the DOJ issued a memorandum ("Cole Memo") setting forth updated guidance reiterating the Ogden Memo and the DOJ's restraint concerning marijuana enforcement by the federal government and therein provided in part:

> In jurisdictions that have enacted laws legalizing marijuana in some form and that have also *implemented strong and effective regulatory and enforcement systems* to control the cultivation, distribution, sale, and possession of marijuana, conduct in compliance with those laws and regulations is less likely to threaten the federal priorities set forth above … In those circumstances, consistent with the traditional allocation of federal-state efforts in this area, *enforcement of state law by state and local law enforcement and regulatory bodies should remain the primary means of addressing marijuana-related activity*.

Cole Memo at 3 (emphasis added); a copy of the Cole Memo is attached hereto as **Exhibit 7**.

55. The Cole Memo highlights the federal government's conviction that marijuana can be used safely under medical supervision when that usage is overseen by state law enforcement and regulatory bodies as it is in Pennsylvania and its commitment not to prosecute entities or persons producing, selling and/or using cannabis in compliance with state laws.

56. In December 2014, Congress enacted a rider to an omnibus appropriations bill commonly referred to as the Rohrbacher-Farr amendment which prohibited the DOJ from using any appropriations provided thereby to prosecute the use, distribution, possession, or cultivation of medical marijuana.

57. The Rohrbacher-Farr amendment provides:

> None of the funds made available in this Act to the Department of Justice may be used, with respect to the States of Alabama, Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida,

> Hawaii, Illinois, Iowa, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, and Wisconsin, to prevent such States from implementing their own State laws that authorize the use, distribution, possession or cultivation of medical marijuana.

See Consolidated and Further Continuing Appropriations Act, 2015 Pub. L. No. 113-235, §538, 128 Stat. 2130, 2217 (2014).

58. The Rohrbacher-Farr amendment was extended, renewed, or re-authorized in every subsequent year.

59. In 2017, the Rohrbacher-Farr amendment was updated to include additional states and territories that had legalized medical marijuana specifically, the 2017 Rohrbacher-Farr amendment provides:

> None of the funds made available in this Act to the Department of Justice may be used, with respect to any of the States of Alabama, Alaska, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming, or with respect to the District of Columbia, Guam, or Puerto Rico, to prevent any of them from implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana.

See Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, §537 (2017).

60. Between 2013 and 2018, an additional twelve states– Minnesota, New York, Georgia, Louisiana, Arkansas, Florida, North Dakota, Ohio, Pennsylvania, Iowa, West Virginia – enacted state laws that legalized medical marijuana in some form.

61. On February 4, 2015, the then U.S. Surgeon General Vivek Murthy stated in a CBS interview that "[w]e have some preliminary data showing that for certain medical conditions and symptoms that marijuana can be helpful."[7]

62. Upon information and belief, the guidance contained in the Ogden and Cole Memos remains the standard utilized by the DOJ today.

63. The Rohrbacher-Farr amendment is currently effective through February 2, 2024.

64. On October 26, 2017, then President Trump declared the opioid crisis a national public health emergency; that same day, then Acting Secretary of Health Eric D. Hargan issued a Determination That a Public Health Emergency Exists nationwide concerning the opioid crisis. A copy of the determination is attached hereto as **Exhibit 8.**

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[7] CBS Interview with U.S. Surgeon General Vivek Murthy, Feb. 4, 2015 at 4:24 – 4:32 https://www.cbsnews.com/news/surgeon-general-dr-vivek-murthy-on-measles-vaccine-marijuana-legalization/ (last accessed Jan. 8, 2024).

65. The DEA reports that "[n]o death from overdose of marijuana has been reported." *See*, Exh. 1.

66. In contrast to medical marijuana, in 2021 alone, there were nearly 17,000 deaths from opioid overdoses, (a category of drugs whose usage does not automatically lead to the denial of Section 8 housing).[8]

67. In June 2018, the FDA approved Epidiolex, a pharmaceutical-grade, marijuana-based cannabidiol (CBD) extract, to treat children suffering from Dravet and Lennox-Gastaut Syndromes.

68. On July 28, 2023, the VA issued "VHA Directive 1315 which provides that "[v]eterans must not be denied VHA services solely because they are participating in a State-approved marijuana program or because they acknowledge use of marijuana." A copy of VHA Directive 1315 is attached hereto as **Exhibit 9**.

69. On or about August 30, 2023, the DHHS recommended to the U.S. DEA that marijuana be re-scheduled to a Schedule III drug under the CSA.

70. Schedule III drugs and substances (i) have a potential for abuse less than the drugs or other substances in Schedules I and II, (ii) have a currently accepted medical use in treatment in the United States, and (iii) abuse of the substance may

[8] CDC, *Opioid Overdose*, https://www.cdc.gov/drugoverdose/deaths/opioid-overdose.html (last accessed Jan. 8, 2024).

lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. §812(b)(3).

71. Today, 44 states, three territories, plus the District of Columbia have legalized medicinal marijuana in at least some form.

72. QHWRA references the CSA to define "a controlled substance" but leaves to the public housing agency or owner to determine whether an applicant is "illegally using" a controlled substance.

73. The QHWRA includes alcohol in section 13661(b) when it allows for the public housing agency or owner to determine whether a member of the family of an applicant's "illegal use (or pattern of illegal use) of a controlled substance or abuse (or pattern of abuse) of alcohol may interfere with the health, safety, or right to peaceful enjoyment of the premises by other residents." 42 U.S.C. §13661(b).

74. Conversely, the QHWRA leaves no discretion to the housing authority or owner under Section 13661(a) where a tenant "shall not be eligible" for housing if convicted of a drug-related criminal activity or under Section 13663(a) for sex offenders where "an owner of federally assisted housing *shall prohibit admission* to such housing for any household that includes any individual who is subject to a lifetime registration requirement under a State sex offender registration program." 42 U.S.C. §§13661(a), 13663(a) (emphasis added).

Pennsylvania's Medical Marijuana Act

75. In 2016, the General Assembly of Pennsylvania in a bi-partisan vote, overwhelmingly passed, and former Governor Wolf enacted the MMJ Act, 35 P.S. §§10231.101, *et seq*. In so doing, the Pennsylvania General Assembly agreed with the FDA and other federal government agencies and specifically found and declared that "[s]cientific evidence suggests that medical marijuana is one potential therapy that may mitigate suffering in some patients and also enhance quality of life." *Id*. at §10231.102(1).

76. The MMJ Act, administered and overseen by the Pennsylvania Department of Health ("Pa. DOH"), provides that patients suffering from serious medical conditions as defined by law and who have been certified to use medical marijuana by Pa. DOH-registered medical practitioners may lawfully use and possess medical marijuana in accordance with the MMJ Act. *Id*. at §10231.303(a). Conversely, Section 304 of the MMJ Act retains criminal liability for the use, possession, manufacture, and sale of marijuana that is not in compliance with the MMJ Act. *Id*. at §10231.304.

77. Section 2103 of the MMJ Act provides that a patient shall not be "subject to arrest, prosecution or penalty in any manner, or *denied any right or privilege*, including civil penalty or disciplinary action by a Commonwealth licensing board or commission, solely for *lawful* use of medical marijuana … or for

any other action taken in accordance with this act". 35 P.S. §10231.2103(a). (emphasis added).

78. On May 12, 2018, after former President Trump declared the opioid epidemic to be a national public health emergency, the Pa. DOH amended its medical marijuana regulations to add "[o]pioid use disorder for which conventional therapeutic interventions are contraindicated or ineffective, or for which adjunctive therapy is indicated in combination with primary therapeutic interventions" a "serious medical condition" eligible to use medical marijuana as a therapeutic medicine. A copy of the pertinent pages of Pa. DOH's notice amending the regulations is attached hereto as **Exhibit 10**.

79. Upon information and belief, the DOJ has not sought enforcement of any federal criminal law against a Pennsylvania-certified, grower/processor, dispensary, laboratory, patient or caregiver for purchasing, possessing, and/or using medical marijuana in accordance with the MMJ Act.

Mary Cease and the Cease Decision

80. In 2018, Ms. Cease – an indigent, sixty-five-year-old, U.S. Navy veteran, with no criminal record, fleeing domestic violence– filed for a family-of-one admission into HAIC's Section 8 Housing Program and, as part of her application, voluntarily disclosed that she lawfully used medical marijuana under

the MMJ Act as an alternative to opioids to treat PTSD and chronic pain – a result of domestic violence and several back surgeries.

81. At the time she applied for admission to the HAIC-administered Section 8 housing program in Indiana County, Pennsylvania, Ms. Cease had an annual income of $11,516.67, and, therefore, she qualified for admission to the Section 8 housing program as an extremely low-income family of one.

82. Today, Ms. Cease's annual income of $11,472.00 would still qualify her as an extremely low-income family of one under HUD's formulations for Indiana County.

83. In June of 2018, the HAIC denied Ms. Cease's application for admission stating, "[w]e must deny program participation as marijuana is still considered to be an illegal substance by the Federal government …" A copy of the June 13, 2018 denial letter is attached hereto as **Exhibit 11**.

84. But for Ms. Cease's lawful use of medical marijuana under state law, she qualified for admission into the HAIC-administered Section 8 Housing Program.

85. In accordance with HUD's and the HAIC's policies and procedures, Ms. Cease participated in an "informal" and "formal" hearing before the HAIC wherein the HAIC affirmed her denial; Ms. Cease then sought review of the HAIC's decision by the Court of Common Pleas for Indiana County ("Trial Court") pursuant

to the Pennsylvania Local Agency Law, 2 Pa.C.S. §752, challenging the HAIC's denial; the Trial Court affirmed the HAIC's denial.

86. On April 26, 2019, Ms. Cease timely filed an appeal of the Trial Court's decision to the Pennsylvania Commonwealth Court, one of Pennsylvania's intermediate appellate courts with exclusive jurisdiction to hear cases involving government entities such as the HAIC.

87. On February 19, 2021, the Commonwealth Court issued its opinion that found that the HAIC, contrary to the Trial Court's decision, was not required to prohibit Ms. Cease's admission under QHWRA but rather the HAIC was required to exercise its discretion to determine the eligibility of an applicant that is lawfully using medical marijuana pursuant to the MMJ Act. Specifically, the Commonwealth Court found that: (1) there is a distinction between the express language of Section 13661(b)(1)(A) of the QHWRA that provides the HAIC "shall establish standards that prohibit admission to the program" versus the HAIC's proffered reading that the QHWRA "shall prohibit admission"; (2) Section 13661(b)(1)(A)'s "illegally using a controlled substance" language is ambiguous in situations such as this, where marijuana is illegal under federal law but legal under state law; (3) that criminal law is a matter left primarily for the states to determine within their own jurisdiction and federalism dictates the federal government must respect Pennsylvania's sovereignty in this respect, and, with respect to marijuana, Pennsylvania decriminalized and

legalized medical marijuana under the MMJ Act; and (4) that Pennsylvania's General Assembly expressly declared that there is scientific evidence that suggests marijuana has acceptable medical uses, thus rendering Section 13661 of the QHWRA obsolete and scientifically flawed. *See* Exh. 2; *Cease*, 247 A.3d at 62-64.

88. The Commonwealth Court held that the HAIC is required to "establish fair and reasonable standards for determining in what circumstances admission to Section 8 housing is prohibited for an applicant who is legally using medical marijuana under state law". *Id.* at 65.

89. The Commonwealth Court even provided the types of standards that should be considered, including: whether it is clearly unlawful or in an unclear legal state such as that involved here; the reason for such use; whether it is being used in accordance with legal requirements; other factors concerning the applicant's background, including behavior during any prior residence in federally subsidized housing; and the presence or absence of any prior criminal record. *Id.* at 62. Following the Commonwealth Court's decision, the HAIC sought further review by the Pennsylvania Supreme Court, but the Supreme Court declined to review the *Cease* decision, thus rendering the Commonwealth Court's decision in *Cease* the law of the land in Pennsylvania.

90. HUD was notified and aware of the *Cease* litigation and the arguments the HAIC was presenting in its defense of its denial of Ms. Cease.

91. At no time during the *Cease* case did HUD seek to intervene in the proceedings, nor did it seek to remove the case to federal court, nor did it seek to pursue federal appellate review of the *Cease* decision.

92. Following the *Cease* decision and the Pennsylvania Supreme Court's declination to hear the HAIC's appeal, the HAIC conferred with HUD for guidance as to how the HAIC should comply with the Pennsylvania state court decision and specifically what standards the HAIC should impose upon new applicants to the Section 8 Housing Program vis-à-vis lawful use of marijuana under the MMJ Act. HUD advised the HAIC that if the HAIC complied with the *Cease* decision, no matter the standards that the HAIC may impose, HUD would cut off all federal funding to the HAIC.

93. As a result of HUD's threats, the HAIC has failed to comply with the *Cease* decision.

94. The HAIC has not and will not create and implement fair and reasonable standards in compliance with the *Cease* decision unless and until the HAIC obtains clarity that complying with the valid Pennsylvania state court decision will not result in the cessation of federal funding by HUD.

Sara Bloch's admission denial

95. In 2023, Ms. Bloch, an indigent single mother who is lawfully using medical marijuana under the MMJ Act, submitted an application with the HAIC for

admission to the HAIC-administered Section 8 housing program in Indiana County, Pennsylvania.

96. Ms. Bloch's annual income is $24,423 qualifying her as a very-low-income family of two.

97. On March 29, 2023, the HAIC denied Ms. Bloch's admittance into the Section 8 Housing Program solely based on her use of medical marijuana. Specifically, the denial stated:

> Your application included a letter from Rebecca Lang, CCM, which indicated that you currently use MMJ (a common acronym for medical marijuana) for chronic pain.
>
> Pursuant to the Housing Authority's Rules and Regulation and guidelines promulgated by the United States Department of Housing and Urban Development (HUD), a new applicant is prohibited admission into the Section 8 program if the applicant is currently a user of a Schedule 1 controlled substance under federal law.

A copy of the HAIC's March 29, 2023 denial letter is attached hereto as **Exhibit 12**.

98. In denying Ms. Bloch's admission, the HAIC did not apply fair and reasonable standards to ascertain whether her admission should be denied but instead relied on HUD's policy memorandum and threats to cut off funding.

COUNT I
DECLARATORY ORDER
QHWRA DOES NOT REQUIRE ADMISSION BE
DENIED FOR THOSE LAWFULLY USING MEDICAL MARIJUANA

99. Plaintiffs incorporate paragraphs 1-98 as if fully set forth herein.

100. To be eligible for admission into a Section 8 housing program, an applicant must meet the income eligibility requirements and the requirements imposed by the QHWRA.

101. Section 13661 of QHWRA provides, in relevant part:

> **(b) INELIGIBILITY OF ILLEGAL DRUG USERS AND ALCOHOL ABUSERS**
>
> **(1) IN GENERAL**
>
> Notwithstanding any other provision of law, a public housing agency or an owner of federally assisted housing, as determined by the Secretary, shall establish standards that prohibit admission to the program *or admission* to federally assisted housing for any household with a member—
>
> (A) who the public housing agency or owner determines is *illegally using* a controlled substance …

42 U.S.C. §13661(b)(1)(A) (emphasis added).

102. QHWRA allows the housing authority or owners to establish criteria under which an applicant could be prohibited admission if such applicant is "illegally using" a controlled substance.

103. There is a distinction between "illegally using a controlled substance" and "using an illegal substance".

104. QHWRA's prohibition focuses on whether the use is illegal, not on whether the substance is illegal.

105. Ms. Bloch and Ms. Cease are lawfully – not illegally – using medical marijuana, a controlled substance.

106. Even if the federal government, in the face of its own contradictory actions, continues to determine that medical marijuana is "illegal", Section 13661 of QHWRA does not expressly require prohibition for applicants illegally using a controlled substance"; rather, QHWRA requires only that the housing authority "establish standards that prohibit admission".

107. In contrast, Section 13663 of QHWRA (Ineligibility of dangerous sex offenders for admission to public housing) provides, in relevant part:

> **(a) IN GENERAL**
> Notwithstanding any other provision of law, an owner of federally assisted housing *shall prohibit admission* to such housing for any household that includes any individual who is subject to a lifetime registration requirement under a State sex offender registration program.

42 U.S.C. §13663(a). (emphasis added).

108. Section 13661's requirement that a housing authority "establish standards that prohibit admission" rather than outright prohibiting admission stands in stark contrast to the express prohibition found in Section 13663 relating to sex offenders.

109. In enacting QHWRA, Congress elected to use different words in Sections 13661(a), 13661(b) and 13663(a).

110. The deployment of different words indicate that Congress' intent for the prohibition of drug-related criminal activity and for sexual offenders was absolute, while prohibition for "illegally using" a controlled substance is subject to the discretion of the housing authority's establishment of standards.

111. Only a guidance memo issued by HUD, which lacks the authority of law, prohibits admission of medical marijuana users.

112. Congress' intent, derived from the plain language of QHWRA, makes clear that QHWRA does not require housing authorities to deny a Section 8 applicant who is using medical marijuana in compliance with state law.

WHEREFORE, Plaintiffs respectfully request this Court (i) issue an order declaring that the Quality Housing and Work Responsibility Act does not require the HAIC and other housing authorities administering Section 8 funding to deny admission to applicants lawfully using medical marijuana in accordance with state law (ii) issue a permanent injunction prohibiting HUD and Secretary Fudge from mandating that housing authorities that receive Section 8 funding automatically deny the admission of an applicant that lawfully uses medical marijuana under state law and (iii) issue a permanent injunction prohibiting HUD from withdrawing funding

from HAIC for establishing standards for admission to housing for low-income persons legally using medical marijuana in Pennsylvania.

COUNT II
DECLARATORY JUDGMENT
HUD HAS VIOLATED THE EQUAL PROTECTION CLAUSE

113. Plaintiffs incorporate paragraphs 1-112 as if fully set forth herein.

114. The Due Process Clause of the Fifth Amendment provides that "No person shall be … deprived of life, liberty, or property, without due process of law". U.S. CONST. amend. V.

115. The Fifth Amendment "forbids the Federal Government to deny equal protection of the laws." *Davis v. Passman*, 442 U.S. 228, 234 (1979).

116. The United States Supreme Court's "approach to Fifth Amendment equal protection claims has always been precisely the same as to equal protection claims under the Fourteenth Amendment." *Weinberger v. Wiesenfeld*, 420 U.S. 636, 636 n. 2 (1975).

117. "Proof of … discriminatory intent or purpose is required to show a violation of the equal protection clause. *Village of Arlington Heights v. Metro. Housing Dev. Corp*., 429 U.S. 252, 265 (1977).

118. Evidence of discriminatory intent or purpose may be demonstrated by several factors including, but not limited to, the "historical background of the decision"; "the specific sequence of events leading up to the challenged decision";

whether there were "[d]epartures from the normal procedural sequence [or s]ubstantive departures"; or "[t]he legislative or administrative history may be highly relevant". *Id*. at 267-268.

119. The CSA makes the manufacturing, distributing, and possession of marijuana illegal because it allegedly has a high potential for abuse, has no accepted medical use, and cannot be used safely even under medical supervision.

120. In contradiction to the criteria a drug must meet in order to be on Schedule I of the CSA, the federal government has acknowledged that marijuana has medical benefits; can be safely used under medical supervision overseen by the states; and does not have a high potential for abuse in that its use has not led to a single overdose death.

121. The federal government has approved patent applications on the premise that marijuana provides medical benefits.

122. The federal government has approved a pharmaceutical medication derived from marijuana.

123. The federal government has instructed federal law enforcement to refrain from enforcing federal law against medical marijuana operators acting in compliance with state law.

124. The federal government has enacted budgetary restrictions to prohibit federal law enforcement from enforcing federal law against medical marijuana operators acting in compliance with state law.

125. The federal government has elected not to enforce the CSA against state-compliant medical marijuana growers, processors, and dispensaries.

126. Upon information and belief, with the exception of HUD, the federal government has not enforced the CSA against medical marijuana grower/processors, dispensaries, laboratories, healthcare institutions, or patients provided such use of medical marijuana complies with state medical marijuana laws.

127. Medical marijuana users who use medical marijuana in compliance with state law and do not seek federally assisted housing from HUD are not penalized for their lawful use of medical marijuana in their pursuit of securing safe, quality, and affordable housing.

128. Medical marijuana users that use medical marijuana in compliance with state law are not disqualified from federal benefits such as medical coverage under the Department of Veteran Affairs or eligibility for SNAP benefits.

129. The only federal agency still punishing persons for using medical marijuana in compliance with state laws, and doing so inconsistently, is HUD in its harsh discrimination of low-income individuals, like Ms. Cease and Ms. Bloch, who

dare to seek affordable housing and relief from their serious medical conditions without turning to highly addictive and dangerous opioids.

130. Ms. Cease has no criminal record whatsoever and is a low-income veteran suffering from chronic pain and post-traumatic stress disorder caused by domestic violence. Ms. Cease chose to legally take marijuana in lieu of opioids.

131. Ms. Cease has been certified by her Pennsylvania-licensed physicians as disabled and unable to work as a result of her suffering from her medical conditions.

132. Ms. Cease lawfully uses medical marijuana under the Pennsylvania MMJ Act.

133. Ms. Cease met the income eligibility requirements to be admitted into the HAIC's Section 8 housing program in Indiana County, Pennsylvania.

134. Ms. Cease's admission into the HAIC's Section 8 housing program was denied due to her lawful use of medical marijuana under state law.

135. Ms. Bloch has never been convicted of a drug-related crime of any kind and is a low-income, single parent who suffers from chronic pain due to psoriatic arthritis and PTSD.

136. In April 2022, the Pennsylvania Department of Labor & Industry, Office of Vocational Rehabilitation determined that Ms. Bloch was an individual

"with Significant Disabilities". A copy of the Department of Labor and Industry's April 2022 determination is attached hereto as **Exhibit 13.**

137. In 2019, Ms. Bloch was certified by her Pennsylvania-licensed doctors to use medical marijuana under Pennsylvania's MMJ Act to treat the symptoms of her medical conditions.

138. Ms. Bloch lawfully uses medical marijuana under the Pennsylvania MMJ Act.

139. On March 29, 2023 Ms. Bloch's application to the HAIC's Section 8 housing program was denied on the basis that she was "currently a user of a Schedule 1 controlled substance under federal law."

140. The HAIC is responsible for implementing and enforcing HUD's policies, guidelines, and regulations.

141. The HAIC denied both Ms. Cease's and Ms. Bloch's applications because HUD policy required the HAIC to deny any Section 8 applicant who uses medical marijuana regardless of whether that applicant's use is in full compliance with state law.

142. *Income-Based Discrimination*. In light of the federal government's decisions over the past 15-plus years to tolerate, accept, and/or prohibit enforcement of the CSA with regard to medical marijuana, including multiple agencies adopting policies that explicitly reject disqualification of lawful medical marijuana users,

HUD's continued enforcement of the CSA premised on QHWRA evinces an intent to discriminate against low-income individuals like Ms. Bloch and Ms. Cease.

143. The impact of HUD's manner of enforcement of the CSA – to preclude admission into Section 8 housing programs – treats low-income Pennsylvania residents differently than more affluent residents because, under the federal government's actions, the more affluent residents are not and cannot be penalized by the federal government for lawfully using medical marijuana.

144. Given that the President and Congress have enacted spending restrictions against pursuing criminal liability for medical marijuana operations and users whose actions comply with comprehensive state-regulated industries, there is no legitimate purpose or rational basis for HUD's misapplied enforcement of the CSA against low-income individuals seeking housing that are lawfully using medical marijuana under state law.

145. *Disability-Based Discrimination*. In light of the federal government's decisions over the past 15-plus years to tolerate, accept, and/or prohibit enforcement of the CSA with regards to medical marijuana, including multiple agencies adopting policies that explicitly reject disqualification of lawful medical marijuana users, HUD's continued erroneous application of the CSA to Section 8 housing applicants evinces an intent to discriminate against disabled individuals like Ms. Bloch and Ms. Cease.

146. The impact of HUD's enforcement of the CSA – to preclude admission into Section 8 housing programs – treats individuals with serious medical conditions that qualify them to use medical marijuana under the Pennsylvania MMJ Act differently than individuals not using medical marijuana under state law because individuals that are ineligible to use medical marijuana may be admitted to Section 8 housing programs while medical marijuana eligible applicants are not.

147. Given that the President and Congress have enacted spending restrictions to stop prosecution of medical marijuana growers, processors, retailers, and users that comply with state laws, there is no legitimate purpose or rational basis for HUD to enforce the CSA in a way that discriminates against disabled individuals that are simply seeking affordable housing and who are lawfully using medical marijuana under state law.

148. There is no rational basis for HUD to enforce the CSA against low-income and disabled Section 8 housing applicants when the majority of the federal government has acknowledged that medical marijuana no longer meets the qualifications to be characterized as a Schedule I substance.

149. Plaintiffs have no remedy at law to stop HUD's application of the CSA or its treatment of low-income and disabled individuals seeking housing and medical marijuana treatment.

150. By reason of the foregoing, Plaintiffs are entitled to issuance of an order and judgment: (i) permanently enjoining HUD from barring Section 8 housing applicants who legally use medical marijuana under state laws and (ii) declaring that HUD's enforcement of the CSA violates the equal protection clause of the Fifth Amendment as it discriminates against low-income and disabled individuals using medical marijuana to treat serious medical conditions. Such an order is necessary because HUD's continued enforcement against such housing applicants, in light of the remainder of the federal government's restraint from enforcing drug laws against lawful medical marijuana businesses and users, is irrational, arbitrary, capricious, and not rationally related to any legitimated governmental interests, and, thus, is unconstitutional.

WHEREFORE, Plaintiffs respectfully request that this Court (i) issue an order declaring that HUD's manner of applying the Controlled Substances Act to the Quality Housing and Work Responsibility Act violates the Equal Protection Clause of the Fourteenth Amendment and (ii) issue a permanent injunction prohibiting HUD's and Secretary Fudge's continued method of enforcement.

COUNT III
DECLARATORY JUDGMENT
VALIDITY OF THE *CEASE* DECISION

151. Plaintiffs incorporate paragraphs 1-150 as if fully set forth herein.

152. "We start with the premise that nothing in the concept of our federal system prevents state courts from enforcing rights created by federal law." *Charles Dowd Box Co. v. Courtney*, 368 U.S. 502, 522 (1962).

153. "Absent proof of prejudice or abuse of discretion, the state courts must be presumed to act in good faith and with judicial wisdom*". Silverman v. Browning*, 414 F. Supp. 80, 88 (D. Conn. 1976), *aff'd* 429 U.S. 876 (1976).

154. The Pennsylvania Commonwealth Court's decision in *Cease*, is a valid state court decision that pronounces the law in Pennsylvania and, thus, HAIC is required to abide by it.

155. The HAIC is considered a local government agency.

156. Under Pennsylvania law, the denial of admission into a Section 8 housing program, including any appeal before the housing authority that issued the denial, is considered an adjudication under the Local Agency Law, 2 Pa. C.S. §752, and, accordingly, the Courts of Common Pleas are the first level of appellate review.

157. In 2018, Ms. Cease properly appealed the adjudication issued by the HAIC to the Indiana County Court of Common Pleas, which ultimately affirmed her denial into the HAIC's Section 8 housing program.

158. Under Pennsylvania law, "the Commonwealth Court shall have exclusive jurisdiction of appeals from final orders of the courts of common pleas" to review cases involving local government civil matters. 42 Pa.C.S. §762(a)(4).

159. In 2019, following the Trial Court's decision affirming her denial, Ms. Cease timely filed an appeal to the Pennsylvania Commonwealth Court.

160. The Pennsylvania Commonwealth Court has jurisdiction to hear cases, including those on appeal, involving federal laws. *See*, 42 Pa.C.S. §762 (Appeals from courts of common pleas).

161. The Pennsylvania Commonwealth Court was properly vested with jurisdiction to hear Ms. Cease's appeal.

162. At no point during the administrative hearing process, the appeal before the Trial Court, the appeal before the Pennsylvania Commonwealth Court, or the HAIC's request for the Pennsylvania Supreme Court to hear an appeal of the Commonwealth Court's decision (such appeal was denied) did HUD seek to intervene, seek to remove the case to federal court, seek appeal to the U.S. Supreme Court, or otherwise participate in the *Cease* proceedings.

163. Following the issuance of the *Cease* decision, HUD threatened to withhold all funding from the HAIC if it complied with the Pennsylvania Commonwealth Court's decision.

164. In issuing the *Cease* decision, the Pennsylvania Commonwealth Court did not abuse its discretion or prejudice any party thereto.

165. Accordingly, the *Cease* decision is valid and enforceable law within the Commonwealth of Pennsylvania such that HUD is required to abide by it.

WHEREFORE, Plaintiffs respectfully request that this Court (i) issue an order declaring that the law set forth in *Cease v. Housing Authority of Indiana County*, 247 A.3d 57 (Pa. Cmwlth. 2021), *pet. for allocatur denied*, 263 A.3d 243 (Pa. 2021), is valid state law to which HUD is bound and (ii) issue a permanent injunction prohibiting HUD and Secretary Fudge from withholding funding from the HAIC for complying with the *Cease* order.

COUNT IV
DECLARATORY JUDGMENT
COLLATERAL ESTOPPEL

166. Plaintiffs incorporate paragraphs 1-165 as if fully set forth herein.

167. Collateral estoppel acts to bar duplicative litigation and, under Pennsylvania law, applies when:

> (1) the issue decided in the prior case must be identical to the one presented in the alter case; (2) there was a final judgment on the merits in the prior action; (3) the party against whom collateral estoppel is asserted was a party to the prior action, or is in privity with a party to the prior action; and (4) the party against whom collateral estoppel is asserted had a full and fair opportunity to litigate the issue in the prior action.

Nationwide Mut. Fire Ins. Co. v. George V. Hamilton, Inc., 471 F.3d 299, 310 (3d Cir. 2009) (internal citations and quotations omitted).

167. A nonparty to an earlier litigation may nevertheless be precluded from re-litigating issues and claims in a subsequent litigation if the nonparty had a substantive legal relationship with the party who participated in the earlier litigation or if the nonparty was adequately represented by someone in the earlier litigation that shared the same interests. *See Taylor v. Strugell*, 553 U.S. 880, 893-895 (2008).

168. Under Pennsylvania law, the HAIC is expressly tasked with "cooperat[ing] with and act[ing] as agent of the Federal Government for the public purposes set out in the [ ] in connection with the acquisition, construction, operation or management of any housing project, or part thereof." 35 P.S. §1550(g).

169. Under federal law, it is the policy of the federal government "to vest in public housing agencies that perform well, the maximum amount of responsibility and flexibility in program administration." 42 U.S.C. §1437(a)(1)(c).

170. HUD delegates to public housing authorities, like HAIC, the enforcement of all eligibility and admission decisions concerning prospective tenants under the Section 8 housing program.

171. In the *Cease* litigation, the HAIC acted as the agent of HUD and represented HUD's interest as it pertained to the eligibility and admission of medical marijuana users under Pennsylvania law.

172. In the *Cease* litigation, the HAIC denied Ms. Cease admission into its Section 8 housing program solely because she used, lawfully under Pennsylvania law, medical marijuana.

173. In the *Cease* litigation, the HAIC's litigation position was that federal law and HUD's regulations preempted the Pennsylvania MMJ Act and that a statutory analysis of QHWRA and the CSA confirmed that medical marijuana users are required to be denied admission into a Section 8 housing program.

174. Throughout the *Cease* litigation, HUD was notified and aware of the HAIC's legal arguments.

175. Throughout the *Cease* litigation, HUD was noticed and aware of Ms. Cease's legal arguments.

176. HUD had an opportunity to intervene in the *Cease* litigation.

177. HUD did not intervene in the *Cease* litigation.

178. In the *Cease* litigation, the Pennsylvania Commonwealth Court's decision expressly rejected the HAIC's arguments that medical marijuana users are prohibited under QHWRA from admission into Section 8 housing programs and that QHWRA and the CSA preempt the Pennsylvania MMJ Act.

179. The HAIC requested that the Pennsylvania Supreme Court consider the *Cease* decision on appeal.

180. HUD did not file an amicus brief in support of the HAIC's appeal, nor did it seek any legal avenue to otherwise participate in the HAIC's appeal.

181. The Pennsylvania Supreme Court declined to take the appeal.

182. HUD did not take any action or require the HAIC to take any action to appeal the *Cease* decision to any federal court.

183. In the *Cease* litigation, the HAIC's and HUD's interests were aligned.

184. In the *Cease* litigation, the HAIC had a legal obligation to represent the interests of HUD.

185. Accordingly, HUD is precluded from re-litigating the issues of preemption and the statutory analysis issue decided in the *Cease* decision.

186. HUD is precluded from compelling the HAIC's compliance on the arguments presented and decided in the *Cease* decision.

WHEREFORE, Plaintiffs seek a declaration that Defendants are collaterally estopped from re-litigating the issues already decided in and by the *Cease* decision and that Defendants are estopped from pulling the HAIC's funding for the same reasons.

COUNT V
DECLARATORY JUDGMENT
REASONABLE ACCOMMODATIONS UNDER STATE LAW

187. Plaintiffs incorporate paragraphs 1-186 as if fully set forth herein.

188. The HAIC is a Pennsylvania registered residential finance authority created pursuant to the Pennsylvania Housing Authorities Law. 35 P.S. §1544.

189. The HAIC is the entity responsible for administering all federal Section 8 housing funding for Indiana County, Pennsylvania.

190. In administering its federal funding for the Section 8 housing program, the HAIC is required to abide by and comply with Pennsylvania laws and regulations.

191. The Pennsylvania Human Relations Act ("PHRA") prohibits discrimination in the leasing of housing on the basis of a disability and requires a reasonable accommodation in the "rules, policies, practices or services as may be necessary to afford equal opportunity "to use and enjoy … housing." 43 P.S. § 955.

192. Under the MMJ Act, no person may be "denied any right or privilege" for the "lawful use of medical marijuana". 35 P.S. § 10231. 2103(a).

193. Individuals like Ms. Cease and Ms. Bloch, who are certified disabled and lawfully use medical marijuana to treat their disability, are required to be afforded reasonable accommodation under the PHRA. 43 P.S. § 955(h)(1).

194. HUD has threatened that it would cut off all Section 8 federal funding if the HAIC admits a Section 8 housing applicant that lawfully uses medical marijuana under the MMJ Act.

195. Based on HUD's threats to cut off funding, the HAIC has refrained from granting Section 8 housing applicants who are lawfully using medical marijuana under the MMJ Act, a reasonable accommodation in the HAIC's admission process.

196. Individuals like Ms. Bloch and Ms. Cease, who are disabled and lawfully treating their disabilities with medical marijuana under the MMJ Act, cannot be discriminated against on the basis that they use medical marijuana. 35 P.S. §10231.2103.

197. It is a reasonable accommodation for HAIC to allow residents to treat their disabilities with a medicine that is legal in Pennsylvania.

198. Accordingly, HUD's threat to cut funding if the HAIC complies with valid state anti-discriminatory laws is unlawful.

WHEREFORE, because the Plaintiffs should not have to choose between safe, effective, medicine and a home, Plaintiffs respectfully request this Court (i) issue an order declaring that the HAIC must afford a reasonable accommodation and may not discriminate against any individual on the basis that they use medical marijuana, and (ii) issue a permanent injunction prohibiting HUD and Secretary Fudge from cutting

off funding for the HAIC for the HAIC's compliance with Pennsylvania's caselaw and anti-discriminatory statutory laws.

Respectfully submitted,

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Dated: January 10, 2024

EXHIBIT 1

Drug Fact Sheet

Marijuana

Overview

Marijuana is a mind-altering (psychoactive) drug, produced by the Cannabis sativa plant. Marijuana contains over 400 chemicals. THC (delta-9-tetrahydrocannabinol) is believed to be the main chemical ingredient that produces the psychoactive effect.

Street names

Aunt Mary, BC Bud, Blunts, Boom, Chronic, Dope, Gangster, Ganja, Grass, Hash, Herb, Hydro, Indo, Joint, Kif, Mary Jane, Mota, Pot, Reefer, Sinsemilla, Skunk, Smoke, Weed, Yerba

Looks like

Marijuana is a dry, shredded green/brown mix of flowers, stems, seeds, and leaves from the Cannabis sativa plant. The mixture typically is green, brown, or gray in color and may resemble tobacco.

Methods of abuse

Marijuana is usually smoked as a cigarette (called a joint) or in a pipe or bong. It is also smoked in blunts, which are cigars that have been emptied of tobacco and refilled with marijuana, sometimes in combination with another drug. Marijuana is also mixed with foods or brewed as a tea.

Affect on mind

When marijuana is smoked, the THC passes from the lungs and into the bloodstream, which carries the chemical to the organs throughout the body, including the brain. In the brain, the THC connects to specific sites called cannabinoid receptors on nerve cells and influences the activity of those cells. Many of these receptors are found in the parts of the brain that influence pleasure, memory, thought, concentration, sensory and time perception, and coordinated movement. The short-term effects of marijuana include problems with memory and learning, distorted perception, difficulty in thinking and problem-solving, and loss of coordination. The effect of marijuana on perception and coordination are responsible for serious impairments in driving abilities. Long-term chronic marijuana use is associated with Amotivational Syndrome, characterized by apathy, impairment of judgment, memory and concentration, and loss of motivation, ambition and interest in the pursuit of personal goals. High doses of marijuana can result in mental confusion, panic reactions and hallucinations. Researchers have also found an association between marijuana use and an increased risk of depression; an increased risk and earlier onset of schizophrenia and other psychotic disorders, especially for teens that have a genetic predisposition.

Affect on body

Short-term physical effects from marijuana use may include sedation, blood shot eyes, increased heart rate, coughing from lung irritation, increased appetite, and decreased blood pressure. Like tobacco smokers, marijuana smokers experience serious health problems such as bronchitis, emphysema, and bronchial asthma. Extended use may cause suppression of the immune system. Because marijuana contains toxins and carcinogens, marijuana smokers increase their risk of cancer of the head, neck, lungs and respiratory track. Withdrawal from chronic use of high doses of marijuana causes physical signs including headache, shakiness, sweating, stomach pains and nausea, as well as

Drug Fact Sheet

Marijuana – cont'd.

behavioral signs including restlessness, irritability, sleep difficulties and decreased appetite.

Drugs causing similar effects

Hashish and hashish oil are drugs made from the cannabis plant that are like marijuana, only stronger. Hashish (hash) consists of the THC - rich resinous material of the cannabis plant, which is collected, dried, and then compressed into a variety of forms, such as balls, cakes, or cookie like sheets. Pieces are then broken off, placed in pipes or mixed with tobacco and placed in pipes or cigarettes, or smoked. The main sources of hashish are the Middle East, North Africa, Pakistan and Afghanistan. Hashish Oil (hash oil, liquid hash, cannabis oil) is produced by extracting the cannabinoids from the plant material with a solvent. The color and odor of the extract will vary, depending on the solvent used. A drop or two of this liquid on a cigarette is equal to a single marijuana joint. Like marijuana, hashish and hashish oil are both Schedule I drugs.

Overdose effects

No death from overdose of marijuana has been reported.

Legal status in the United States

Marijuana is a Schedule I substance under the Controlled Substances Act. Schedule I drugs are classified as having a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use of the drug or other substance under medical supervision. Marinol, a synthetic version of THC, the active ingredient found in the marijuana plant, can be prescribed for the control of nausea and vomiting caused by chemotherapeutic agents used in the treatment of cancer and to stimulate appetite in AIDS patients. Marinol is a Schedule III substance under the Controlled Substances Act. Schedule III drugs are classified as having less potential for abuse than the drugs or substances in Schedules I and II, and have a currently accepted medical use in treatment in the U.S., and abuse of the drug may lead to moderate or low physical dependence or psychological dependence.

Common places of origin

Marijuana is grown in the United States, Canada, Mexico, South America and Asia. It can be cultivated in both outdoor and in indoor settings.

EXHIBIT 2

247 A.3d 57
Commonwealth Court of Pennsylvania.

Mary CEASE, Appellant
v.
HOUSING AUTHORITY OF INDIANA COUNTY

No. 519 C.D. 2019
|
Argued February 13, 2020
|
Decided February 19, 2021

Synopsis

Background: Applicant for Section 8 housing benefits sought review of decision by county housing authority, which denied her application based on her use of medical marijuana authorized under the Pennsylvania Medical Marijuana Act. The Court of Common Pleas, Indiana County, No. 11894 CD 2018, William J. Martin, President Judge, affirmed housing authority's decision. Applicant appealed.

The Commonwealth Court, No. 519 C.D. 2019, Bonnie Brigance Leadbetter, President Judge Emerita, held that housing authority was not required by the federal Quality Housing and Work Responsibility Act (QHWRA) to deny benefits based on medical marijuana use, but rather was only required to establish reasonable standards for denying Section 8 benefits based on such use.

Affirmed in part, vacated in part, and remanded.

Patricia A. McCullough, J., filed a dissenting opinion.

Procedural Posture(s): On Appeal; Review of Administrative Decision.

***58** Appealed from No. 11894 CD 2018, Common Pleas Court of the County of Indiana, Martin, President Judge.

Attorneys and Law Firms

Kevin J. McKeon and Judith D. Cassel, Harrisburg, for Appellant.

Kevin R. Gaydos, Indiana, for Appellee.

BEFORE: HONORABLE PATRICIA A. McCULLOUGH, Judge, HONORABLE MICHAEL H. WOJCIK, Judge, HONORABLE BONNIE BRIGANCE LEADBETTER, Senior Judge

Opinion

OPINION BY SENIOR JUDGE LEADBETTER [1]

Mary Cease appeals from an order of the Court of Common Pleas of Indiana County that affirmed the decision of the Housing Authority of Indiana County (1) denying her application for housing assistance under the United States Department of Housing and Urban Development's (HUD) Housing Choice Voucher Program, commonly referred to as Section 8 [2] and (2) ***59**

concluding that she was a new applicant to the program under Section 13661 of the Quality Housing and Work Responsibility Act (QHWRA), 42 U.S.C. § 13661. The Authority's denial was based upon the statement in her application for admission that she used medical marijuana. We affirm the order to the extent that it determined that Cease was a new applicant to the Section 8 program, vacate it to the extent that it affirmed the Authority's denial of Cease's application, and remand this matter for the Authority to carry out its mandate under Section 13661 of QHWRA: (1) to establish standards for determining when and on what basis admission is prohibited for an applicant legally using medical marijuana pursuant to a valid Medical Marijuana Identification Card; and (2) to apply those standards when determining Cease's eligibility for Section 8 housing.

Cease is a disabled veteran of the United States Navy, with no prior criminal record. She suffers from post-traumatic stress disorder and chronic back pain for which she has endured multiple surgeries. (Apr. 11, 2019 Trial Court Op. at 1.) Pursuant to Section 501 of the Pennsylvania Medical Marijuana Act, [3] the Pennsylvania Department of Health issued Cease a Medical Marijuana Identification Card. It is undisputed that her card is valid and that Pennsylvania law permits her to obtain and use medical marijuana to treat her conditions. [4] (*Id*. at 2.)

Over the years, Cease has participated in at least two federally funded and subsidized housing programs. The first is HUD's Section 8 program, which the Authority administers in Indiana County. Cease participated in the Section 8 program while living in Nanticoke, Pennsylvania and Wilkes-Barre, Pennsylvania, and applied for admission once again in Indiana County. (*Id*.) The second is the United States Department of Agriculture's (USDA) rural rent supplement program, [5] pursuant to which Cease currently lives at Clymer House Apartments in Clymer, Pennsylvania. Although the USDA's program offers a rental assistance subsidy comparable to what HUD offers qualified residents in metropolitan areas, HUD's regulations do not govern the USDA's program. (*Id*.)

In November 2017, Cease submitted an "Initial Application for Housing Assistance – All Programs" to the Authority for Section 8 housing. (Nov. 30, 2017 Initial Application; Reproduced Record "R.R." at 15a.) In its acknowledgment, the Authority advised Cease that it was placing her on a waiting list with an average waiting time of six months to one year and that "[t]he application process and requirements for eligibility are explained in the policies available for your review at our office." (Nov. 30, 2017 Letter at 1; R.R. at 17a.) In April 2018, the Authority informed Cease that there was an opening in Section 8 housing and requested that she provide a full application to determine her eligibility. (Apr. 10, 2018 Letter at 1; R.R. at 19a.) Cease complied, including a copy of her Medical Marijuana Identification Card with the application.

***60** In denying the application, the Authority stated: "We must deny program participation as marijuana is still considered to be an illegal substance by the Federal government and costs associated with marijuana medical treatments *cannot* be considered in calculation of adjusted income." (June 13, 2018 Letter at 1; R.R. at 37a) (emphasis in original). At Cease's request, informal and formal hearings followed. Ultimately, the Authority upheld its denial based solely on the illegality of marijuana under federal law. (Sept. 26, 2018 Letter at 1; R.R. at 279a.) In so doing, the Authority agreed that Cease's income was well below its "extremely low" threshold and conceded that she met the income standards for Section 8 housing. [6] The Section 8 Coordinator for Indiana County, Holly Hall, testified that the Authority denied Cease admission based on the federal government's classification of marijuana as an illegal drug and HUD's memos regarding the use of medical marijuana. (Sept. 18, 2018 Hearing, Notes of Testimony "N.T." at 49-50; R.R. at 87a-88a.) In particular, Hall seemed to rely upon Exhibit 9, directed to all public housing agencies and specifically pertaining to the Section 8 program. In the 2011 memo, HUD sought to provide guidance regarding the use of medical marijuana in states that have enacted laws permitting the use of medical marijuana and stated that new admissions of medical marijuana users was prohibited. (*Id*., Ex. 9; R.R. at 4a.) Further, HUD stated that state laws legalizing medical marijuana directly conflict with the admission requirements set forth in QHWRA and are thus subject to federal preemption. [7] (*Id*.)

On appeal, the trial court took additional testimony confirming Cease's status as a former Section 8 program participant in Luzerne County before moving to Indiana County. Following legal argument, it affirmed the Authority's denial of Cease's

application for Section 8 housing and determination that she was a new applicant to the program. Cease's appeal to this Court followed.

Cease raises two issues, one with three subparts. In summary and reordered for ease of analysis, the first issue is whether Cease is a new applicant under Section 13661 of QHWRA or an existing participant under Section 13662. [8] If Cease is a new applicant, then she poses the issue of whether Section 13661 requires that the Authority deny her housing based on legal medical marijuana use or whether it may exercise discretion. If the decision to deny housing on that basis is discretionary, then she poses the issue of whether the Authority should afford her accommodation for a disability under the Pennsylvania Human Relations Act (PHRA) [9] and the Pennsylvania Medical Marijuana Act. Cease's second issue is whether the lawful use of medical marijuana constitutes "illegally using a ***61** controlled substance" such that the use can form the basis for exclusion from the Section 8 program.

Congress created the Section 8 program in 1974 for "the purpose of aiding low-income families in obtaining a decent place to live and of promoting economically mixed housing" by providing low-income families with assistance payments, or subsidies, to enable them to rent units in the private housing market. Section 8(a) of the Housing and Community Development Act of 1974, 42 U.S.C. § 1437f(a). Pursuant to the program, HUD funds and regulates state or local governmental public housing agencies by distributing federal funds to the agencies, which, in turn, distribute the funds by contracting with property owners to subsidize a portion of a program participant's rent. *See* 42 U.S.C. § 1437f.

In 1998, Congress enacted QHWRA, which, *inter alia*, amended the Housing and Community Development Act of 1974 [10] by requiring public housing agencies to establish standards to consider when determining admission to and termination from the Section 8 program. *See* 42 U.S.C. §§ 13661-13664. Section 13661(b)(1)(A) of QHWRA, "Screening of applicants for federal assisted housing," provides:

> (b) Ineligibility of illegal drug users and alcohol abusers.
>
> (1) Notwithstanding any other provision of law, a public housing agency or an owner of federally assisted housing, as determined by the Secretary, *shall establish standards that prohibit admission to the program* or admission to federally assisted housing for any household with a member--
>
> (A) who the public housing agency or owner determines is illegally using a controlled substance.

42 U.S.C. § 13661(b)(1)(A) (emphasis added). Section 13662(a)(1) of the QHWRA, 42 U.S.C. § 13662(a)(1), "Termination of tenancy and assistance for illegal drug users and alcohol abusers in federally assisted housing," provides:

> (a) In general. Notwithstanding any other provision of law, a public housing agency or an owner of federally assisted housing (as applicable) shall establish standards or lease provisions for continued assistance or occupancy in federally assisted housing that allow the agency or owner (as applicable) to terminate the tenancy or assistance for any household with a member--
>
> (1) who the public housing agency or owner determines is illegally using a controlled substance[.]

42 U.S.C. § 13662(a)(1).

As for which of the aforementioned provisions of QHWRA applies to Cease, we note that she was a participant in the USDA's rural rent supplement program when she applied for Section 8 housing in Indiana County. In other words, she was neither an existing Section 8 participant nor a participant in any federally subsidized housing program administered by the Authority at the time of her Section 8 application. Consequently, we determine that the Authority properly treated Cease as a new applicant to the Section 8 program such that the screening provision in Section 13661 of QHWRA applied. We turn to an analysis of that provision.

As noted above, Section 13661(b)(1)(A) of QHWRA provides that the Authority "shall establish standards that prohibit admission to the program[.]" 42 U.S.C. § 13661(b)(1)(A). Notably, there is a difference between "shall establish standards that prohibit admission" and "shall prohibit ***62** admission." Otherwise, the term "establish standards" is entirely meaningless. The object of statutory construction is to ascertain and to effectuate legislative intent. Section 1921(a) of the Statutory Construction Act of 1972, 1 Pa.C.S. § 1921(a). "[W]hen the words of a statute are clear and free from all ambiguity, the letter of it is not to be disregarded under the pretext of pursuing its spirit." 1 Pa.C.S. § 1921(b). Generally, the best indication of legislative intent is the plain language of a statute. *Malt Bevs. Distribs. Ass'n v. Pa. Liquor Control Bd.*, 601 Pa. 449, 457, 974 A.2d 1144, 1149 (2009). *See also U.S. v. Gonzales*, 520 U.S. 1, 6, 117 S.Ct. 1032, 137 L.Ed.2d 132 (1997) (Where "[g]iven a straightforward statutory command, there is no reason to resort to legislative history.").

By way of contrast, Section 13663(a) of QHWRA, pertaining to sex offenders, provides that "[n]otwithstanding any other provision of law, an owner of federally assisted housing *shall prohibit admission* to such housing for any household that includes any individual who is subject to a lifetime registration requirement under a State sex offender registration program." 42 U.S.C. § 13663(a) (emphasis added). Clearly, there is no discretion in prohibiting admission to such applicants. Accordingly, we construe the mandate in Section 13661(b)(1)(A) of QHWRA as allowing for flexibility to determine when and on what basis admission is prohibited, rather than mandating an outright prohibition. In other words, for purposes of Section 13661(b)(1)(A), the Authority must establish standards for determining when and on what basis admission is prohibited for a Section 8 housing applicant who the Authority determines is illegally using a controlled substance. *See Nation v. Trump*, 818 F. App'x 678, 679-80 (9th Cir. 2020) ("QHWRA requires that owners of federally-assisted housing establish certain occupancy standards pertaining to illegal drug use for residents. *See generally* 42 U.S.C. §§ 13661-62."). Such standards must take into account factors such as the nature of the substance, i.e., whether it is clearly unlawful or in an unclear legal state such as that involved here; the reason for such use; whether it is being used in accordance with legal requirements; other factors concerning the applicant's background, including behavior during any prior residence in federally subsidized housing; and the presence or absence of any prior criminal record.

As for marijuana's legal status, the federal Controlled Substances Act (CSA) [11] classifies marijuana as a Schedule I controlled substance and it is unlawful for any person to knowingly or intentionally possess a controlled substance. Section 841(a)(1) of the federal CSA, 21 U.S.C. § 841(a)(1). Although there have been considerable efforts to reclassify marijuana under federal law, it has remained a Schedule I drug ever since its initial classification. Additionally, there has been resistance to efforts to make exceptions for the use of medical marijuana in federally-funded public housing. *See Nation v. Trump*, 395 F. Supp. 3d 1271 (N.D. Cal. 2019), *aff'd*, 818 F. App'x 678 (9th Cir. 2020) (where former HUD housing fund recipient claimed that HUD's application of the federal CSA against medical marijuana was unconstitutional, court confirmed that QHWRA referred to the CSA to define the term "controlled substance," that the CSA defined that term as a drug or other substance in one of its five schedules, and that marijuana was classified as a Schedule I drug under the CSA); *Forest City Residential Mgmt. v. Beasley*, 71 F. Supp. 3d 715 (E.D. Mich. 2014) (where Section 8 ***63** housing recipient was legally using medical marijuana under state law, court acknowledged that the CSA contained no provision allowing for the medical use of marijuana, held that the CSA preempted the Michigan Medical Marihuana Act, [12] and determined that the Fair Housing Act [13] did not require a federally assisted housing complex to grant the recipient a reasonable accommodation to use medical marijuana in such a complex).

Nonetheless, we are not bound by decisions of lower federal courts in other jurisdictions. Cease possesses a valid Pennsylvania Medical Marijuana Identification Card authorizing her to legally obtain and use medical marijuana under medical supervision, and the Authority does not dispute that she has a valid medical basis for her use and that it is properly prescribed and supervised. Consequently, we find the term "illegally using a controlled substance" to be ambiguous here where her use is prohibited by the federal government but permitted under state law. [14] Criminal law is primarily a matter for the states to determine within their own jurisdictions. "Federalism, central to the constitutional design, adopts the principle that both the National and State Governments have elements of sovereignty the other is bound to respect." *Arizona v. United States*, 567 U.S. 387, 398, 132 S.Ct. 2492, 183 L.Ed.2d 351 (2012). As the Pennsylvania Supreme Court recently observed:

> [T]he core principle of federalism recogniz[es] dual sovereignty between the tiers of government. *See United States v. Davis*, 906 F.2d 829, 832 (2d Cir. 1990) ("The states and the national government are distinct political communities, drawing their

> separate sovereign power from different sources, each from the organic law that established it. Each has the power, inherent in any sovereign, independently to determine what shall be an offense against its authority and to punish such offenses."). In enacting the [Pennsylvania Medical Marijuana ***64** Act], the Pennsylvania Legislature proceeded pursuant to its independent power to define state criminal law and promote the health and welfare of the citizenry.

Gass v. 52nd Jud. Dist., —— Pa. ——, 232 A.3d 706, 714 (2020). Consequently, "while possession and use of marijuana remains illegal under federal law even for medical purposes, ... the federal [CSA] does not (and could not) require states to enforce it." *Id.* at 714.

In *Gass*, our Supreme Court unanimously declared that the Lebanon County Court of Common Pleas, 52nd Judicial District's "Medical Marijuana Policy" prohibiting the active use of medical marijuana by individuals under court supervision, such as probationers, was, in both its original and amended forms, contrary to the immunity afforded under the Pennsylvania Medical Marijuana Act and, therefore, could not be enforced. In other words, the Court determined that a local policy could not usurp a state law simply by reference to a federal law such as the federal CSA. *Id.* Accordingly, the *Gass* Court held: "While the circumstances are certainly uneasy -- since possession and use of medical marijuana remains a federal crime -- we find that the [52nd Judicial] District cannot require state-level adherence to the federal prohibition, where the General Assembly has specifically undertaken to legalize the use of medical marijuana for enumerated therapeutic purposes." *Id.* We believe the same is true of the Authority. [15]

Moreover, the pertinent provisions of QHWRA are based on the obsolete and scientifically flawed premise that marijuana "has no currently accepted medical use in treatment in the United States" and that "there is a lack of accepted safety for use of marijuana under medical supervision." Section 812(b)(1)(A-C) of the federal CSA, 21 U.S.C. § 812(b)(1)(A-C). *See also U.S. v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 121 S.Ct. 1711, 149 L.Ed.2d 722 (2001) (recognizing that there is no medical necessity exception to the federal prohibition against manufacturing and distributing marijuana). In contrast, the General Assembly in Section 102(1) of the Pennsylvania Medical Marijuana Act declared: "Scientific evidence suggests that medical marijuana is one potential therapy that may mitigate suffering in some patients and also enhance quality of life." 35 P.S. § 10231.102(1). Consequently, given the current circumstances regarding the medically accepted use and ambiguous status of medical marijuana, establishment of fair and reasonable standards regarding the use of that substance under medical supervision is particularly called for here.

Accordingly, we affirm the trial court's order to the extent that it determined that ***65** Cease was a new applicant but vacate the order to the extent that it affirmed the Authority's denial of Cease's application. We remand this matter to the trial court with directions to remand to the Authority to do what QHWRA mandates and establish fair and reasonable standards for determining in what circumstances admission to Section 8 housing is prohibited for an applicant who is legally using medical marijuana under state law, and to apply those standards with respect to Cease's individual circumstances when determining Cease's eligibility for the Section 8 program.

ORDER

AND NOW, this 19th day of February, 2021, we hereby AFFIRM the order of the Court of Common Pleas of Indiana County, in part, VACATE the order, in part, and REMAND this matter to the trial court with directions to remand to the Housing Authority of Indiana County in accordance with the foregoing opinion.

Jurisdiction relinquished.

DISSENTING OPINION BY JUDGE McCULLOUGH

I must respectfully dissent. The Majority goes to great lengths to explain why Congress's use of the phrase "shall establish standards that prohibit" in section 13361 of the federal Quality Housing and Work Responsibility Act (QHWRA), [1] means a Public Housing Authority (PHA) has "flexibility" to decide whether to admit an illegal drug user (as defined in the federal Controlled Substance Act [2] (CSA)) into a Section 8 housing program. [3] By avoiding the rules of statutory interpretation, the Majority assigns to the phrase "shall establish standards that prohibit" a meaning that Congress plainly did not intend.

The Majority also disregards some very basic constitutional and jurisprudential concepts to arrive at the desired conclusion that Mary Cease (Cease), a user of medical marijuana, is not "illegally using a controlled substance" under the QHWRA. The fact that Pennsylvania's Medical Marijuana Act [4] (MMA) legalizes the use of medical marijuana in limited situations is immaterial to the disposition of this case. The CSA (which illegalizes medical marijuana as a Schedule I drug) applies here because the QHWRA is a federal statute.

Interpretation of the QHWRA

The Section 8 housing program is a federally funded and supervised rent subsidy program for low-income tenants which is administered by the United States Department of Housing and Urban Development (HUD). The QHWRA is a federal statute. It establishes the parameters for a PHA, such as the Housing Authority of Indiana County (HAIC), to follow when considering admission to, and termination from, the Section 8 housing program. *See* 42 U.S.C. §§ 13661-13664.

Section 13661 of the QHWRA, titled "Screening of applicants for federally assisted housing," applies to new applicants. [5] By its plain language, section 13661 of the QHWRA ***requires*** owners of federally assisted housing to ***deny admission*** to a new ***66** applicant if she, or a household member, is illegally using a controlled substance. With regard to "admission to the program," section 13361(b)(1)(A) provides, in this regard, as follows:

> Notwithstanding any other provision of law, a public housing agency or an owner of federally assisted housing, as determined by the Secretary, ***shall establish standards that prohibit admission*** to the program or admission to federally assisted housing for any household with a member--
>
> (A)***who the public housing agency or owner determines is illegally using a controlled substance***;
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> ****

42 U.S.C. § 13661(b)(1)(A) (emphasis added).

In contrast to the mandatory grounds for ***prohibiting admission*** to a Section 8 program set forth in section 13661, section 13662 of the QHWRA, titled "Termination of tenancy and assistance for illegal drug users and alcohol abusers in federally assisted housing," grants the PHA ***discretion*** to determine when and on what basis an ***existing participant's*** tenancy may be terminated if she is illegally using a controlled substance or abusing alcohol. Section 13662(a)(1) provides, in this regard, as follows:

> Notwithstanding any other provision of law, a public housing agency or an owner of federally assisted housing (as applicable), ***shall establish standards*** or lease provisions for continued assistance or occupancy in federally assisted housing ***that allow*** the agency or owner (as applicable) ***to terminate the tenancy*** or assistance for any household with a member--
>
> (1) ***who the public housing agency or owner determines is illegally using a controlled substance***;
>
> ****

42 U.S.C. § 13662(a)(1) (emphasis added).

In my view, the phrases "***shall establish standards that prohibit***" (section 13661) and "***shall establish standards that allow***" (section 13662) in the sections dealing with illegal drug use make it clear precisely when Congress intended for a PHA to have discretion and when a PHA lacks that discretion.

Congress has a strict drug policy when it comes to the admission of current drug users (as defined by the CSA) into Section 8 housing. As stated by the federal courts, the import of the QHWRA and its accompanying regulations "is to protect public housing from criminal elements, especially drug activity, which could adversely affect the community." *Bennington Housing Authority v. Bush*, 182 Vt. 133, 933 A.2d 207, 213 (2007). *See also Eastern Carolina Regional Housing Authority v. Lofton*, 369 N.C. 8, 789 S.E.2d 449, 452 (2016) (observing that, "like everyone else, individuals who live in federally subsidized housing are entitled to be free from 'any criminal activity that threatens the health, safety, or right to peaceful enjoyment of the premises' "). When it comes to deciding whether to ***admit a current drug user*** into a Section 8 housing program, PHAs have no discretion. They must deny admission. [6] *See Campbell v. Minneapolis Public Housing Authority,* 168 F.3d 1069, 1076 (8th Cir. 1999) (holding that the Minneapolis Public Housing Authority was "***obligated to exclude [applicant] from public*** ***67*** ***housing if it 'ha[d] reasonable cause to believe' that, at the time of his application, he was using illegal drugs or abusing alcohol in a manner that 'may interfere with the health, safety, or right to peaceful enjoyment of the premises by other residents of the project***' ") (emphasis added).

Contrariwise, when it comes to ***eviction***, *i.e.*, the potential ***displacement*** of an ***existing tenant*** and/or her entire household, PHAs are given discretion to "***establish standards that allow***" those tenants or their families to remain in Section 8 housing despite the violation, for example, by issuing warnings, or setting probation periods. This is because of the hardship that arises when tenants lose their housing. *Bennington Housing* (observing that a PHA certainly may evict an entire family for the misdeeds of one member, but it need not do so); *Lofton* (holding that housing authority was required to exercise its discretion before pursuing tenant's eviction from federally subsidized apartment for lease violation arising from third party's drug-related activity).

Despite the clarity with which Congress has indicated when a PHA has discretion, the Majority concludes that section 13661 of the QHWRA allows for "flexibility" to determine when and on what basis admission is prohibited, rather than mandating an outright prohibition to current users of illegal drugs.

The Majority's interpretation is based on its observation that Congress used the phrase "***shall prohibit***" in another section of the QHWRA (prohibiting sex offender's admission to Section 8 housing). Section 13663(a) of the QHWRA states that "notwithstanding any other provision of law, an owner of federally assisted housing ***shall prohibit*** admission to such housing" to registered sex offenders. 42 U.S.C. § 13663(a) (emphasis added).

The Majority concludes that, given the different wording, the two phrases, "***shall prohibit***" (in section 13663) and "***shall establish standards that prohibit***" (in section 13661), must have different meanings. Comparing the language of section 13661 (admission to Section 8 housing) with section 13663 (prohibiting sex offender's admission to Section 8 housing), the Majority concludes that, if Congress intended for Section 8 admission to be denied to current drug users, then it would have stated this as plainly as it did in section 13663 by using the phrase "***shall prohibit***." The Majority reasons that since Congress did not use the words "***shall prohibit***" in section 13661, it must have, therefore, meant for PHAs to have some degree of discretion to admit Cease as a new applicant under section 13661, notwithstanding her current use of medical marijuana. Otherwise, the Majority reasons, the phrase "shall establish standards" is meaningless.

The Majority's interpretive principles are unconvincing. First, the Majority does not explain how section 13661's language is ambiguous in context. Rather, the Majority compares section 13661 (***shall establish standards that prohibit***) with section 13663 (***shall prohibit***) – and based on the differences, arrives at the meaning of "***shall establish standards that prohibit***."

If statutory language is "clear and free from ambiguity, the letter of it is not to be disregarded under the pretext of pursuing its spirit." 1 Pa.C.S. § 1921(b). Thus, when the words of a statute have a plain and unambiguous meaning, it is this meaning which is the paramount indicator of legislative intent. When interpreting federal statutes, courts must read the statutory language in its

proper context and not view it in isolation. *McCarthy v. Bronson*, 500 U.S. 136, 139, 111 S.Ct. 1737, 114 L.Ed.2d 194 (1991). The Majority's approach in ***68** only comparing and contrasting language used in a different section of the QHWRA is directly contrary to these principles. *Roethlein v. Portnoff Law Associates, Ltd.*, 623 Pa. 1, 81 A.3d 816, 822 (2013) (disapproving lower court's focus on two words).

The Majority focuses on the ***presence*** of the phrase "shall establish standards" in section 13661 and its ***absence*** in section 13663, instead of considering the plain and unambiguous language of section 13661, which is the paramount indicator of legislative intent. When the phrase is read in full and in context, it is clear that "***shall establish standards that prohibit***" simply and plainly means that ***whatever*** standards a PHA establishes for admission into a Section 8 housing program, those standards ***must prohibit*** admission if the applicant is determined to be illegally using a controlled substance. There is absolutely nothing ambiguous with that statement. Nevertheless, by isolating the phrase "shall establish standards" from the rest of the sentence, which describes the type of standards the PHA must establish, *i.e.*, "standards ***that prohibit***" – the Majority is able to contrive an ambiguity where none exists. This approach is in clear contravention of well-established rules of statutory interpretation.

Ironically, under the Majority's interpretation, the phrases: "shall establish standards that prohibit" (section 13661) and "shall establish standards that allow" (section 13662) – would mean the exact same thing (*i.e.*, PHAs have flexibility and discretion to admit into program and terminate tenancy) – simply because both sections include the phrase "shall establish standards." If that was the case, then the language "***that allow***" and "***that prohibit***" which follows "shall establish standards" would be rendered entirely meaningless. "The courts must construe every statute, if possible, to give effect to all of its provisions so that none are rendered mere surplusage." *White v. Associates in Counseling & Child Guidance, Inc.*, 767 A.2d 638, 642 (Pa. Cmwlth. 2001) (citing 1 Pa.C.S. §§ 1921(a) and 1922(a)).

Even if there was an ambiguity, which I submit there is not, I disagree with the Majority's view that the language in section 13661 ("***shall establish standards that prohibit***") is so dissimilar to the language in section 13663 ("***shall prohibit***") – such that we can conclude that Congress intended dissimilar results. There is no reason in law or logic to construe section 13661 in a different manner than section 13663. The phrase "***shall establish standards that prohibit***" in section 13661 is no less definite than the language used in section 13663 ("***shall prohibit***"). Substantively, ***establishing standards that prohibit*** is precisely the same in legal effect as ***prohibiting*** outright. It is a distinction without a difference.

Finally, applying the Majority's own logic, if Congress wanted to give PHAs discretion under section 13661 to ***allow*** drug users ***admission*** to Section 8 housing, it would have used the same language it used in section 13662 to grant that discretion, which states that a PHA "***shall establish standards that allow***" the PHA to terminate an existing tenancy for any household with a member who the PHA determines is illegally using a controlled substance ...." 42 U.S.C. § 13662(a)(1). However, Congress did not include such language in section 13661. Instead it used "***that prohibit***," which has the exact opposite meaning of "***that allow***."

It is also noteworthy that HUD's regulation, which sets forth standards for PHA tenant selection criteria, 24 C.F.R. § 960.204, support the conclusion that the phrase "***establish standards that prohibit"*** means that the PHA is ***required to deny*** admission to persons engaging in ***69** illegal use of drugs. "Persons engaging in illegal use of a drug" is listed ***under the regulation defining circumstances, which require the denial of admission,*** and states under no uncertain terms that the PHA is required to deny admission to persons ***engaging in illegal use of a drug***. This section of the regulations provides, in pertinent part:

> **§ 960.204 Denial of admission for criminal activity or drug abuse by household members.**
>
> ***(a) Required denial of admission.***
>
> ***
>
> ***(2) Persons engaging in illegal use of a drug. The PHA must establish standards that prohibit admission of a household to the PHA's public housing program if:***

> ***(i) The PHA determines that any household member is currently engaging in illegal use of a drug***[7] (For purposes of this section, a household member is "currently engaged in" the criminal activity if the person has engaged in the behavior recently enough to justify a reasonable belief that the behavior is current) ....

24 C.F.R. § 960.204(a)(2) (emphasis added.)

Subsection (a)(4) of these same regulations require PHAs to "***establish standards that prohibit admission***" to Section 8 housing ***for registered sex offenders***. If the Majority is correct that the phrase "must establish standards" means that the PHA has "discretion" or "flexibility" to make decisions, then PHAs ***would*** have discretion to admit registered sex offenders, which is directly the opposite of what the Majority is arguing based on the language in section 13663 of the QHWRA, which provides that PHAs "***shall prohibit***" admission to registered sex offenders. This pertinent section of the regulations, which relates to sex offenders, provides in part:

> (4) Persons subject to sex offender registration requirement. ***The PHA must establish standards that prohibit admission to the PHA's public housing program if any member of the household is subject to a lifetime registration requirement under a State sex offender registration program***. In the screening of applicants, the PHA must perform necessary criminal history background checks in the State where the housing is located and in other States where household members are known to have resided. (See part 5, subpart J of this title for provisions concerning access to sex offender registration records.)

24 C.F.R. § 960.204(a)(4) (emphasis added).

Based on the foregoing, I disagree with the Majority's interpretation of section 13661 of the QHWRA. To me, it is abundantly clear that PHAs have no discretion to admit persons who engage in the illegal use of drugs, as defined in the governing federal law. Rather, PHAs are required to deny admission to Section 8 housing if the ***70** PHA determines that the applicant or any household member is currently engaging in illegal use of drugs.

Under Federal Law, Cease is Illegally Using a Controlled Substance

I also disagree with the Majority's conclusion that Cease is not illegally using a controlled substance for determining her eligibility for Section 8 housing under the QHWRA. Cease's possession and use of medical marijuana violates the CSA.

Even though medical marijuana is legal *in certain situations* under Pennsylvania law pursuant to section 2103(a) of the MMA, 35 P.S. § 10231.2103(a), Congress has explicitly classified "marihuana" as an illegal Schedule I controlled substance in the CSA. Section 812(c) of the CSA, SCHEDULE I (c)(10). Along with Morphine, Peyote, LSD, and nearly 100 other Schedule I controlled substances, Congress has declared that marijuana (cannabis): (1) has a high potential for abuse; and (2) ***has no currently accepted medical use in treatment in the United States***. 21 U.S.C. § 812(b)(1)(A)-(C). Categorizing marijuana as a Schedule I drug reflects Congress's conclusion that marijuana "lack[s] any accepted medical use, and [that there is an] absence of any accepted safety for use in medically supervised treatment." *Gonzales v. Raich*, 545 U.S. 1, 14, 125 S.Ct. 2195, 162 L.Ed.2d 1 (2005) (citing 21 U.S.C. § 812(b)(1)); *see also United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 121 S.Ct. 1711, 149 L.Ed.2d 722 (2001) (recognizing that there is no medical necessity exception to the federal prohibition against manufacturing and distributing marijuana).

Despite efforts to reclassify marijuana, it has remained a Schedule I drug since the enactment of the federal CSA. *Raich*, 545 U.S. at 14-15, n.23, 125 S.Ct. 2195 (summarizing "considerable efforts," ultimately unsuccessful, to reschedule marijuana). It

follows then that medical marijuana use is considered "illegally using a controlled substance" under federal law for purposes of the QHWRA. Because ***Congress*** has directly and unambiguously spoken in the federal QHWRA regarding the illegality of using medical marijuana, our inquiry should end here. The plain language of the QHWRA is clear and unambiguous regarding Cease's illegal use of a controlled substance. Cease's use and possession of medical marijuana is illegal under federal law. Because Cease is an illegal drug user under the CSA, HAIC was required to deny her application for admission to Section 8 housing under section 13661 of the QHWRA, notwithstanding that Pennsylvania has legalized medical marijuana in the MMA.

In finding that the phrase "illegally using a controlled substance" is ambiguous, the Majority reasons that medical marijuana is legal in Pennsylvania and Cease is a Pennsylvania citizen. The Majority draws the distinction in this case on the principle of federalism that the states and the federal government operate in their respective sphere of governance. However, the Majority fails to recognize that, due to the applicability of a federal statute, we are bound to interpret the QHWRA in accordance with federal law, as it is inherently a matter of federal concern. The maxim that "[f]ederalism, central to the constitutional design, adopts the principle that both the National and State Governments have elements of sovereignty the other is bound to respect," *Arizona v. United States,* 567 U.S. 387, 398, 132 S.Ct. 2492, 183 L.Ed.2d 351 (2012), cuts both ways.

The Majority also overstates the breadth of the MMA. Contrary to the Majority's position, the MMA has not made medical marijuana legal in Pennsylvania in every situation. It only legalized it to the ***71** extent that the legislature has declared it so. Section 304(a) of the MMA states that "***[e]xcept as provided in section 303, section 704, Chapter 19 or Chapter 20 [of the MMA], the use of medical marijuana is unlawful and shall, in addition to any other penalty provided by law, be deemed a violation of the Act of April 14, 1972 (P.L. 233, No. 64), [as amended, 35 P.S. §§ 780.101-780.144,] known as the Controlled Substance, Drug, Device and Cosmetic Act."*** (emphasis added.)

The Majority also believes the CSA is based on the "obsolete and scientifically flawed" premise that marijuana has no currently accepted medical use in treatment in the United States and there is a lack of accepted safety or use of marijuana under medical supervision. The Majority oversteps its bounds. Although the Majority feels that the United States Congress and federal administrative bodies "got it wrong" when drafting the federal statutes and regulations—it is not for this Court to hold marijuana should be considered a medically-acceptable drug, as a matter of federal law, or that marijuana should be removed as an illegal substance in the federal CSA. Stripped of its language, the Majority essentially finds that there is no rational basis for the federal CSA and that, therefore, it is unconstitutional. This is tantamount to overruling an act of the United States Congress and well-established precedent from the United States Supreme Court which has held that Congress can regulate the possession of medicinal marijuana through the CSA pursuant to its authority under the Commerce Clause. *See Raich.*

The Majority's position simply cannot be reconciled with the Supremacy Clause of the United States Constitution,[8] which dictates that the federal law prevails over state law. The Supremacy Clause[9] prevents this Court from applying the Pennsylvania MMA to discern the meaning of "illegally using a controlled substance."

Finally, HAIC participates in a federal program under which it receives federal funds. As a condition of receiving such funds, ***it must comply with federal requirements***. By encouraging HAIC to flout the CSA, the Majority is placing HAIC's right to receive federal funding at risk.

Congress has seen fit to exclude medical marijuana users from Section 8 housing based on its belief that medical marijuana has no medical uses. This Court cannot override Congress's clear intent to prohibit ***all*** marijuana users from admission into Section 8 housing for reasons that this Court has no authority to question. While sympathetic to Cease's situation, this Court—no matter how inequitable the factual scenario of a case may be—lacks the constitutional authority to do so.

For these reasons, I dissent.

All Citations

247 A.3d 57

Footnotes

1 This opinion was reassigned to the author on September 18, 2020.

2 Section 8(a) of the Housing and Community Development Act of 1974, 42 U.S.C. § 1437f(a).

3 Act of April 17, 2016, P.L. 84, 35 P.S. § 10231.501.

4 Section 303(a) of the Pennsylvania Medical Marijuana Act provides generally that the use or possession of medical marijuana is lawful and that "[n]otwithstanding any provision of law to the contrary, use or possession of medical marijuana as set forth in [the Act] is lawful within this Commonwealth." 35 P.S. § 10231.303(a).

5 Section 514 of the Housing and Community Development Act of 1974, 42 U.S.C. § 1490a, created the USDA's rural rent supplement program.

6 Derived from Social Security benefits, Cease's annual income was $9,240 and below the "extremely low" income level of $13,450. (Sept. 18, 2018 Hearing, Notes of Testimony "N.T." at 20; R.R. at 58a.)

7 The memo lists fourteen states and the District of Columbia as having laws that legalize the use of medical marijuana. In 2011, Pennsylvania was not one of those states. Currently, there are at least thirty-three states and the District of Columbia that have legalized medical marijuana.

8 Implicit in this issue is the parties' belief that Section 13662 of QHWRA affords a public housing agency discretion to terminate the tenancy or assistance to an existing participant who the agency or owner determines is illegally using a controlled substance.

9 Act of October 27, 1955, P.L. 744, *as amended*, 43 P.S. §§ 951-963.

10 42 U.S.C. §§ 1401-1440.

11 21 U.S.C. §§ 801-971.

12 Mich. Comp. Laws §§ 333.26421-333.26430.

13 42 U.S.C. §§ 3601-3631.

14 Of course, even in the Commonwealth's body of laws, there are statutory conflicts and/or legislative failures to act with respect to accommodations for users of medical marijuana. In *Harrisburg Area Community College v. Pennsylvania Human Relations Commission*, 245 A.3d 283 (Pa. Cmwlth. 2020) ("*HACC*"), this Court considered the effect of HACC's drug-testing requirement for candidates in its nursing program on a nursing student lawfully using medical marijuana under the Pennsylvania Medical Marijuana Act. We addressed the issue of whether the anti-discrimination provisions of the PHRA and the Pennsylvania Fair Educational Opportunities Act (PFEOA), Act of July 17, 1961, P.L. 776, *as amended*, 24 P.S. §§ 5001-2010, required accommodation of the student's lawful use of medical marijuana. We held that the legalization of medical marijuana in Pennsylvania in the Pennsylvania Medical Marijuana Act did not require an accommodation for its use under either Section 5(i)(1) of the PHRA, 43 P.S. § 955(i)(1), or Section 4(a)(3) of the PFEOA, 24 P.S. § 5004(a)(3), noting that the General Assembly could have amended the language of those acts to require

accommodation but chose not to do so. *Id*. at 291 and 292–93. In her concurring opinion, Judge Covey urged the General Assembly to amend both the PHRA and the PFEOA so the benefits it created in the Pennsylvania Medical Marijuana Act "for the citizens of this Commonwealth are not illusory or applicable only in limited circumstances; thereby, creating an egregious result as is demonstrated in the instant case." *HACC*, 245 A.3d at 299 (Covey, J. concurring). Judge Covey opined that "[t]he conflict among these statutes has created an absurd result in requiring Pennsylvania citizens to choose the benefits of medical marijuana or the protections of the PHRA and the PFEOA." *Id*. at 299–300 (Covey, J. concurring).

15 In *Beasley*, 71 F. Supp. 3d 715, the United States District Court for the Eastern District of Michigan considered how much deference to afford a January 2011 memorandum opinion issued by HUD to the Office of Fair Housing and Equal Opportunity regarding the medical use of marijuana and reasonable accommodation in federal public and assisted housing. Concluding that the HUD memorandum was not a statute, regulation, or formal judicial interpretation, the federal district court rejected the higher level of deference set forth in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*., 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). Instead, the federal district court concluded that the HUD memorandum was a more informal medium not intended to have the force of law and, therefore, afforded it the lesser level of deference set forth in *Skidmore v. Swift & Company*, 323 U.S. 134, 140, 65 S.Ct. 161, 89 L.Ed. 124 (1944). Accordingly, the federal district court, per *Skidmore*, gave weight to "HUD's conclusion that a medical marijuana accommodation [was] not reasonable under the Fair Housing Act because it would constitute a fundamental alteration in the nature of a [public housing agency] or owner's operations." *Beasley*, 71 F. Supp. 3d at 730.

1 42 U.S.C. § 13661.

2 21 U.S.C. §§ 801-971.

3 Section 8(a) of the Housing and Community Development Act of 1974 (HCDA), 42 U.S.C. § 1437f(a).

4 Act of April 17, 2016, P.L. 84, 35 P.S. §§ 10231.101-10231.2110.

5 I have no objection to the Majority's conclusion that Cease was a "new applicant" to the Section 8 program.

6 Notably, federal regulations permit PHAs to overlook ***drug history*** and ***prior drug convictions*** if the person is no longer engaging in drug abuse or has been rehabilitated. 24 C.F.R. § 960.204(a)(1). But here, it is undisputed that Cease is a ***current*** user of medical marijuana.

7 Under federal law, marijuana is a Schedule I controlled substance with "no currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B). Significantly, Congress also has delineated those controlled substances which it does recognize as having a currently accepted medical use in the United States. These are listed in Schedules II-V. Marijuana is not listed in Schedules II-V. In other words, Congress has determined that not only is marijuana listed as a prohibited Schedule I drug, it also chose not to include it on the list of those substances that it recognizes as having any accepted medical use. *See Harrisburg Area Community College v. Pennsylvania Human Relations Commission*, 245 A.3d 283, 288–89 (Pa. Cmwlth. No. 654 C.D. 2019, filed Oct. 29, 2020).

8 U.S. Const. art. 1, § 8, cl. 3.

9 U.S. Const. art. 6, cl. 2.

EXHIBIT 3

U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
WASHINGTON, DC 20410-5000

OFFICE OF PUBLIC AND INDIAN HOUSING

January 31, 2022

Ms. Judith D. Cassel
100 North Tenth Street
Harrisburg, PA 17101-2440

Dear Ms. Cassel:

On behalf of Secretary Marcia L. Fudge, thank you for your letter on September 27, 2021, regarding the prohibition of medical marijuana use by applicants in the Housing Choice Voucher (HCV) program.

Marijuana is a controlled substance under federal law. Pursuant to the statutory requirement at 42 USC §§13661, the Department of Housing and Urban Development's (HUD) Office of Public and Indian Housing (PIH) issued the attached memorandum providing guidance to all HUD Field Offices and Public Housing Agencies on February 10, 2011. This guidance remains current for all PHAs regarding the use of medical marijuana in the Public Housing and HCV programs.

Please contact Ashley Matthews via email at *Ashley.E.Matthews@hud.gov* if you have questions about this guidance.

Sincerely,

Danielle Bastarache
Danielle Bastarache
Deputy Assistant Secretary
Office of Public Housing and Voucher Programs

Attachment

EXHIBIT 4

US006630507B1

(12) **United States Patent**
Hampson et al.

(10) **Patent No.: US 6,630,507 B1**
(45) **Date of Patent: Oct. 7, 2003**

(54) **CANNABINOIDS AS ANTIOXIDANTS AND NEUROPROTECTANTS**

(75) Inventors: **Aidan J. Hampson**, Irvine, CA (US); **Julius Axelrod**, Rockville, MD (US); **Maurizio Grimaldi**, Bethesda, MD (US)

(73) Assignee: **The United States of America as represented by the Department of Health and Human Services**, Washington, DC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/674,028**

(22) PCT Filed: **Apr. 21, 1999**

(86) PCT No.: **PCT/US99/08769**

§ 371 (c)(1),
(2), (4) Date: **Feb. 2, 2001**

(87) PCT Pub. No.: **WO99/53917**

PCT Pub. Date: **Oct. 28, 1999**

Related U.S. Application Data

(60) Provisional application No. 60/082,589, filed on Apr. 21, 1998, and provisional application No. 60/095,993, filed on Aug. 10, 1998.

(51) **Int. Cl.**[7] **A61K 31/35**
(52) **U.S. Cl.** **514/454**
(58) **Field of Search** 514/454

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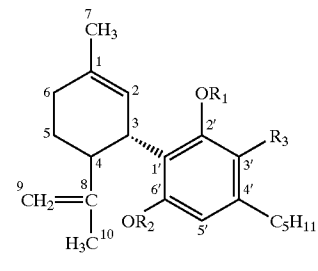
(List continued on next page.)

Primary Examiner—Kevin E. Weddington
(74) *Attorney, Agent, or Firm*—Klarquist Sparkman, LLP

(57) **ABSTRACT**

Cannabinoids have been found to have antioxidant properties, unrelated to NMDA receptor antagonism. This new found property makes cannabinoids useful in the treatment and prophylaxis of wide variety of oxidation associated diseases, such as ischemic, age-related, inflammatory and autoimmune diseases. The cannabinoids are found to have particular application as neuroprotectants, for example in limiting neurological damage following ischemic insults, such as stroke and trauma, or in the treatment of neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and HIV dementia. Nonpsychoactive cannabinoids, such as cannabidoil, are particularly advantageous to use because they avoid toxicity that is encountered with psychoactive cannabinoids at high doses useful in the method of the present invention. A particular disclosed class of cannabinoids useful as neuroprotective antioxidants is formula (I) wherein the R group is independently selected from the group consisting of H, CH_3, and $COCH_3$.

(I)



26 Claims, 7 Drawing Sheets

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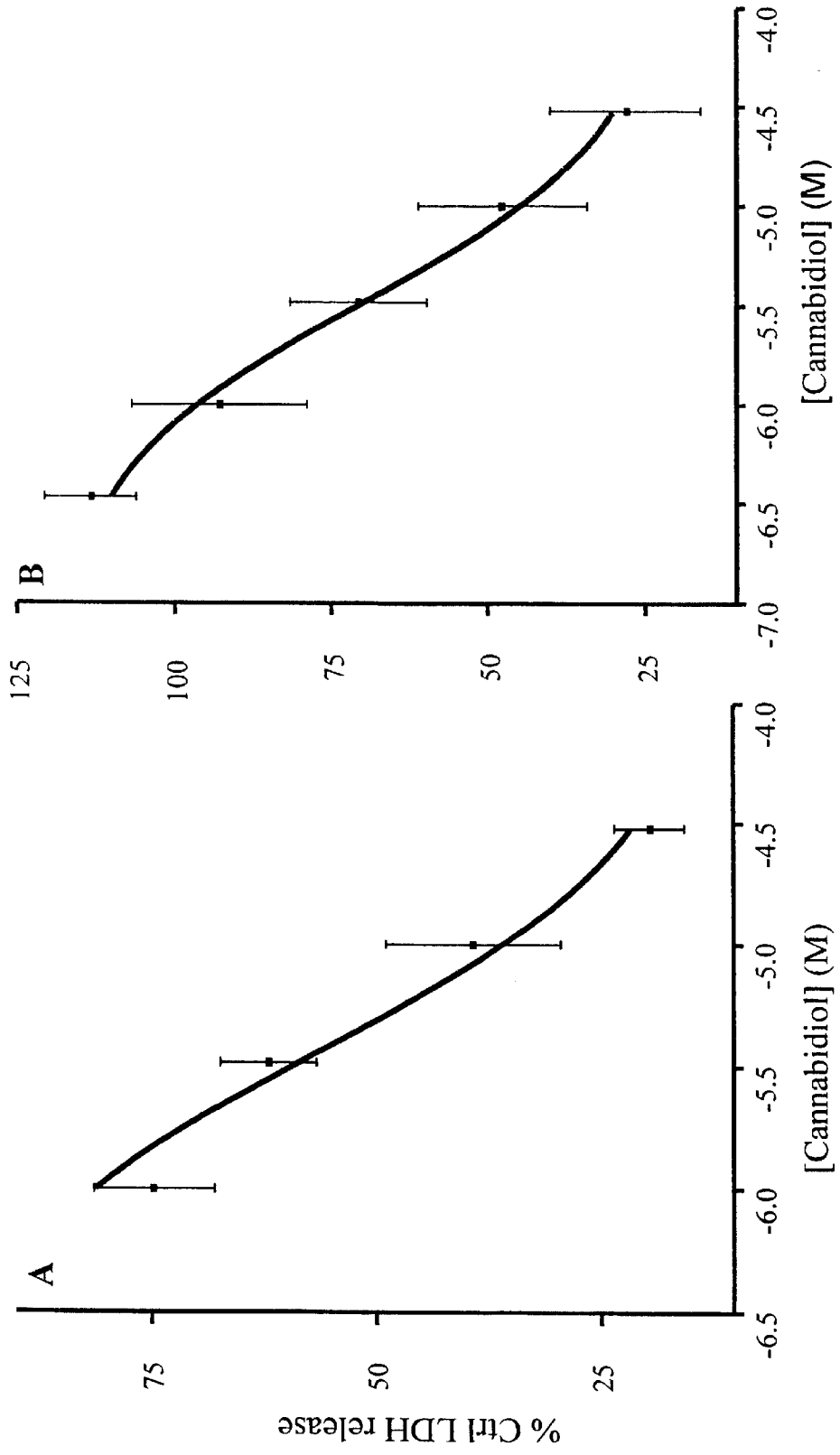
FIG. 1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B
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125
100
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50
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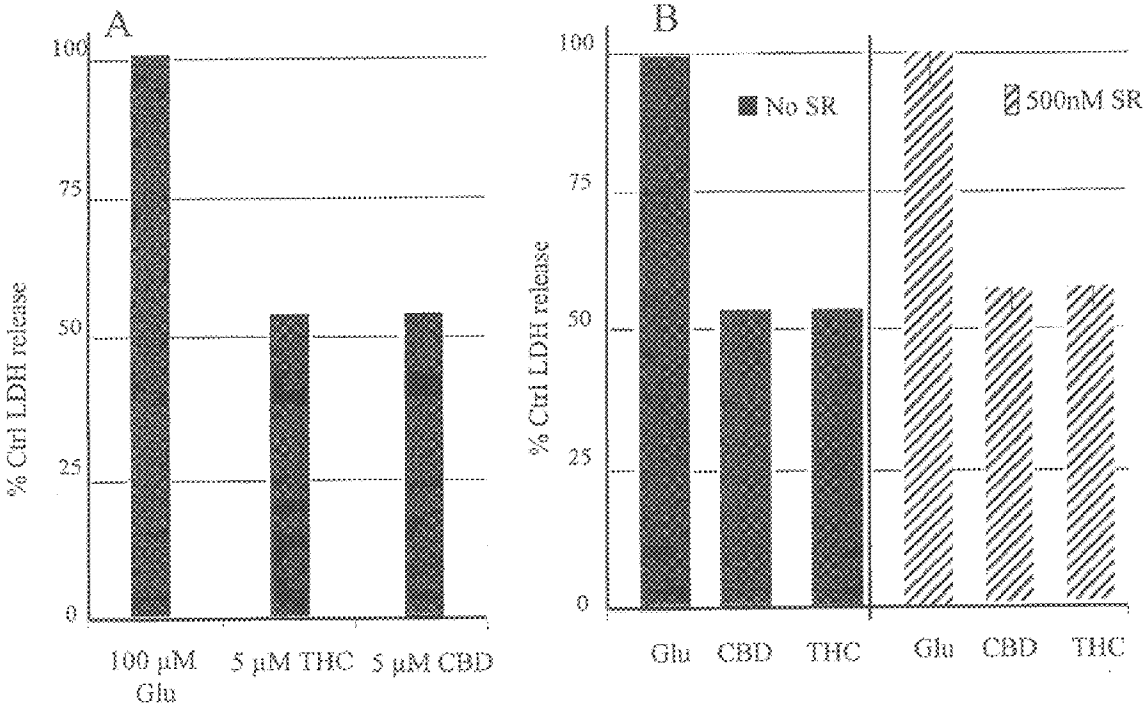
-7.0
[Cannabidiol] (M)

FIG. 2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75
50
25
0
% Ctrl LDH release
100 μM Glu
5 μM THC
5 μM CBD
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CBD
THC
Glu
CBD
THC

FIG. 4

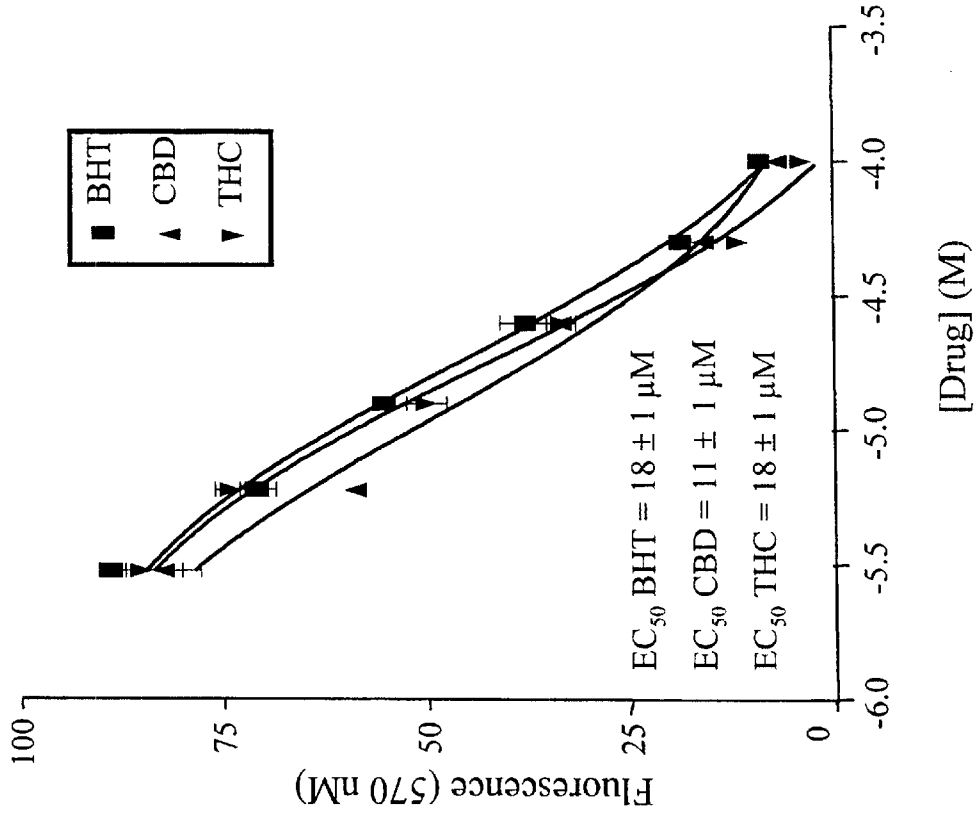

BHT
CBD
THC
EC50 BHT = 18 ± 1 µM
EC50 CBD = 11 ± 1 µM
EC50 THC = 18 ± 1 µM
Fluorescence (570 nM)
100
75
50
25
0
-6.0
-5.5
-5.0
-4.5
-4.0
-3.5
[Drug] (M)

FIG. 3

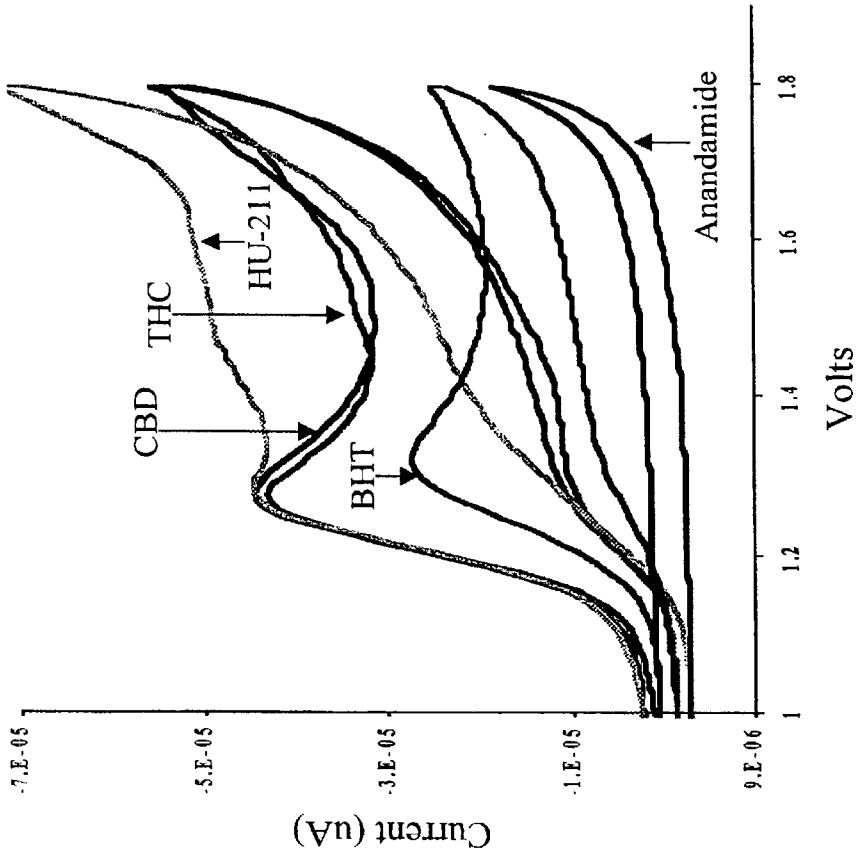

HU-211
THC
CBD
BHT
Anandamide
Current (uA)
-7.E-05
-5.E-05
-3.E-05
-1.E-05
9.E-06
1
1.2
1.4
1.6
1.8
Volts

FIG. 5

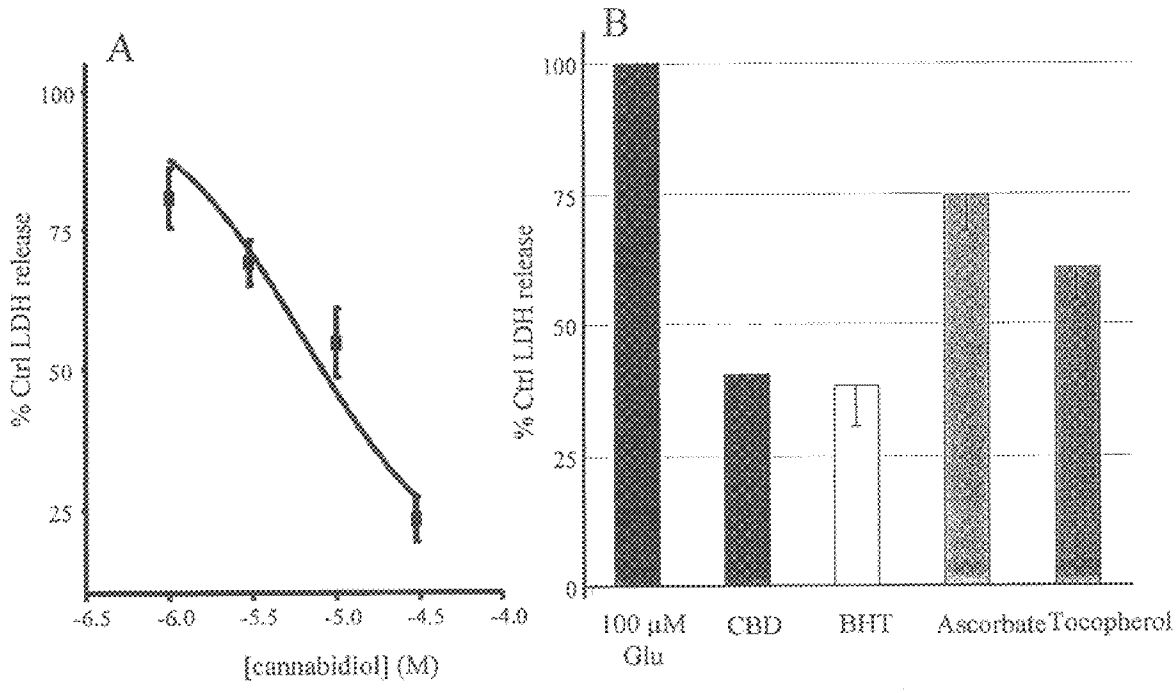

A
100
75
50
25
% Ctrl LDH release
-6.5
-6.0
-5.5
-5.0
-4.5
-4.0
[cannabidiol] (M)
B
100
75
50
25
0
% Ctrl LDH release
100 µM Glu
CBD
BHT
Ascorbate
Tocopherol

FIG. 6

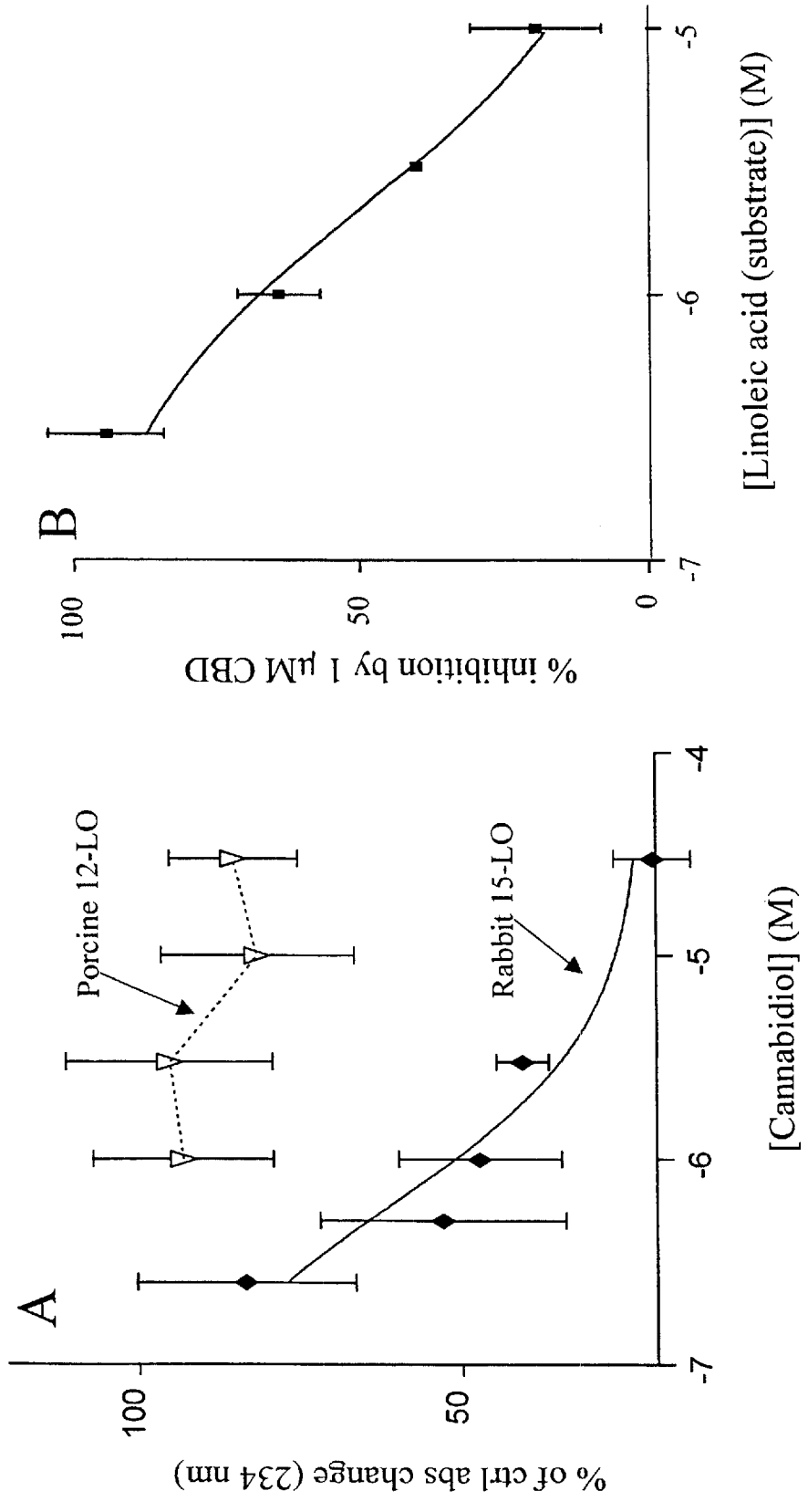

A
% of ctrl abs change (234 nm)
100
50
-7
-6
-5
-4
[Cannabidiol] (M)
Porcine 12-LO
Rabbit 15-LO
B
% inhibition by 1 μM CBD
100
50
0
-7
-6
-5
[Linoleic acid (substrate)] (M)

FIG. 7

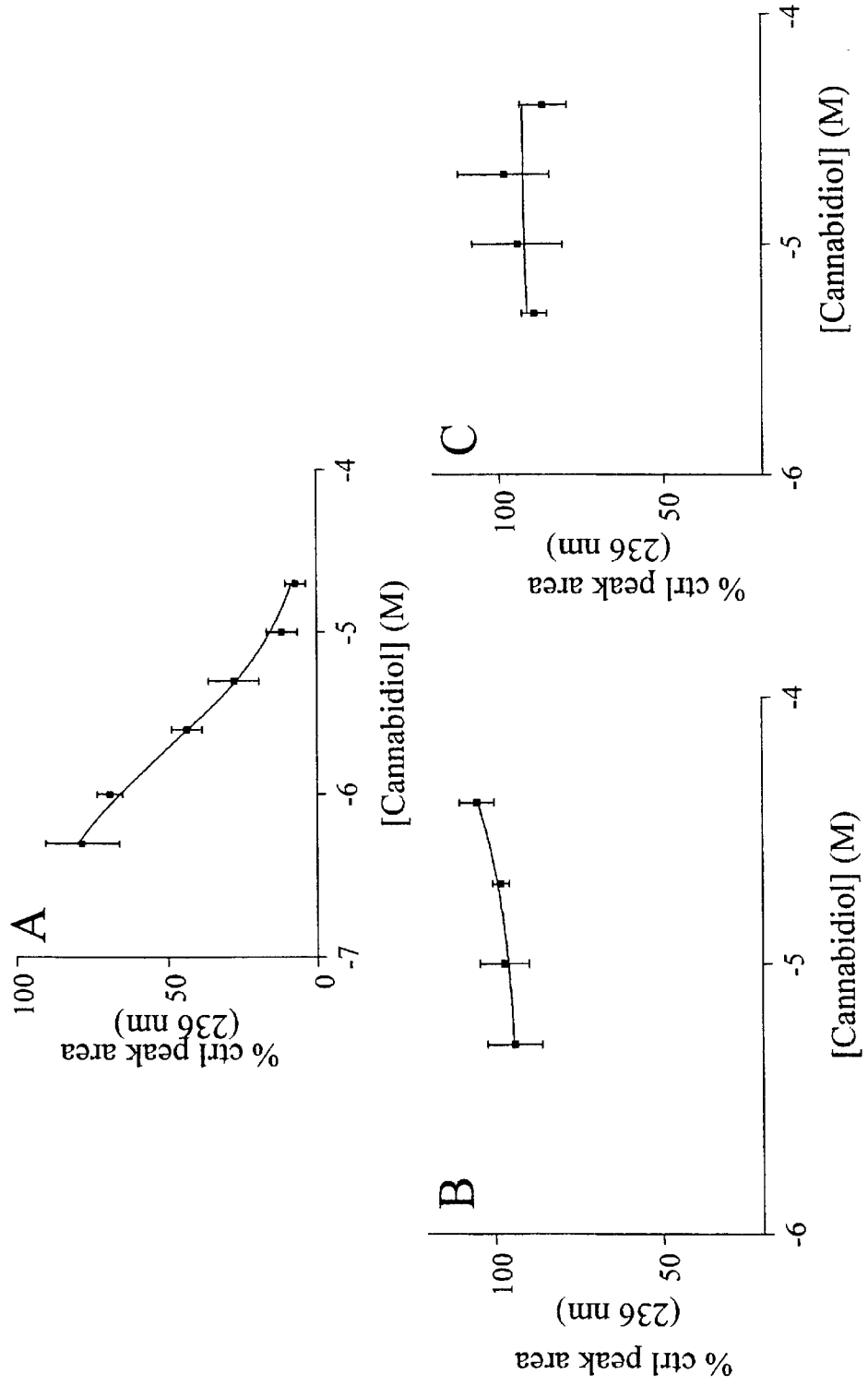
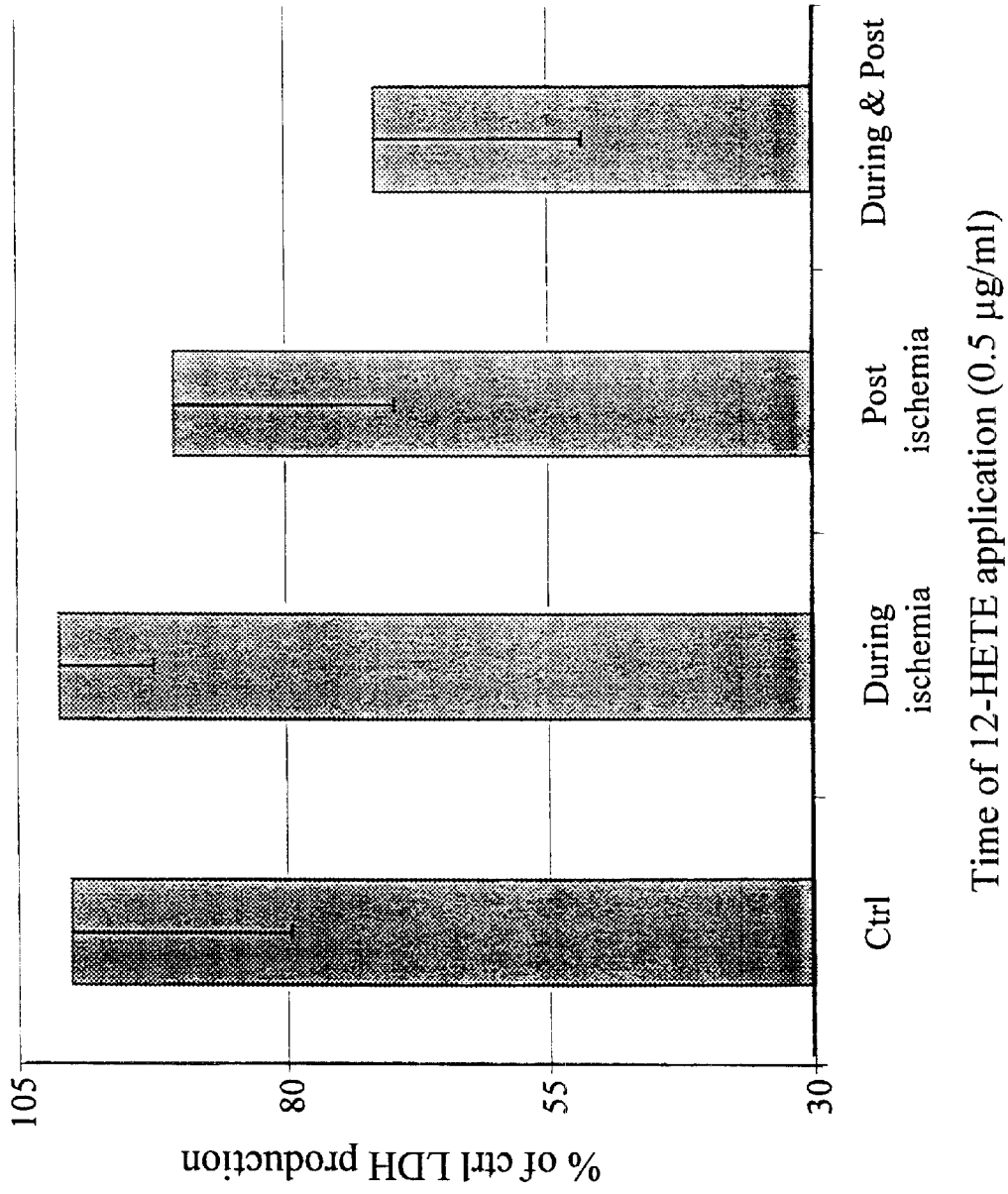


FIG. 8


% of ctrl LDH production
105
80
55
30
Ctrl
During ischemia
Post ischemia
During & Post
Time of 12-HETE application (0.5 µg/ml)

CANNABINOIDS AS ANTIOXIDANTS AND NEUROPROTECTANTS

This application is a 371 of PCT/US99/08769 filed Apr. 21, 1999, which claims benefit of No. 60/082,589 filed Apr. 21, 1998, which claims benefit of No. 60/095,993 filed Aug. 10, 1998.

FIELD OF THE INVENTION

The present invention concerns pharmaceutical compounds and compositions that are useful as tissue protectants, such as neuroprotectants and cardioprotectants. The compounds and compositions may be used, for example, in the treatment of acute ischemic neurological insults or chronic neurodegenerative diseases.

BACKGROUND OF THE INVENTION

Permanent injury to the central nervous system (CNS) occurs in a variety of medical conditions, and has been the subject of intense scientific scrutiny in recent years. It is known that the brain has high metabolic requirements, and that it can suffer permanent neurologic damage if deprived of sufficient oxygen (hypoxia) for even a few minutes. In the absence of oxygen (anoxia), mitochondrial production of ATP cannot meet the metabolic requirements of the brain, and tissue damage occurs. This process is exacerbated by neuronal release of the neurotransmitter glutamate, which stimulates NMDA (N-methyl-D-aspartate), AMPA (α-amino-3-hydroxy-5-methyl-4-isoxazole propionate) and kainate receptors. Activation of these receptors initiates calcium influx into the neurons, and production of reactive oxygen species, which are potent toxins that damage important cellular structures such as membranes, DNA and enzymes.

The brain has many redundant blood supplies, which means that its tissue is seldom completely deprived of oxygen, even during acute ischemic events caused by thromboembolic events or trauma. A combination of the injury of hypoxia with the added insult of glutamate toxicity is therefore believed to be ultimately responsible for cellular death. Hence if the additive insult of glutamate toxicity can be alleviated, neurological damage could also be lessened. Anti-oxidants and anti-inflammatory agents have been proposed to reduce damage, but they often have poor access to structures such as the brain (which are protected by the blood brain barrier).

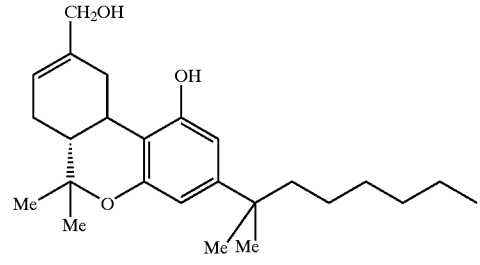
Given the importance of the NMDA, AMPA and kainate receptors in the mechanism of injury, research efforts have focused on using antagonists to these receptors to interfere with the receptor mediated calcium influx that ultimately leads to cellular death and tissue necrosis. In vitro studies using cultured neurons have demonstrated that glutamate receptor antagonists reduce neurotoxicity, but NMDA and AMPA/kainate receptor antagonists have different effects. Antagonists to NMDAr prevent neurotoxicity if present during the glutamate exposure period, but are less effective if added after glutamate is removed. In contrast, AMPA/kainate receptor antagonists are not as effective as NMDA antagonists during the glutamate exposure period, but are more effective following glutamate exposure.

Some of the research on these antagonists has focused on cannabinoids, a subset of which have been found to be NMDA receptor antagonists. U.S. Pat. No. 5,538,993 (3S, 4S-delta-6-tetrahydrocannabinol-7-oic acids), U.S. Pat. No. 5,521,215 (sterospecific (+) THC enantiomers), and U.S. Pat. No. 5,284,867 (dimethylheptyl benzopyrans) have reported that these cannabinoids are effective NMDA receptor blockers. U.S. Pat. No. 5,434,295 discloses that the 1,1 dimethylheptyl (DMH) homolog of [3R,4R]-7-hydroxy-

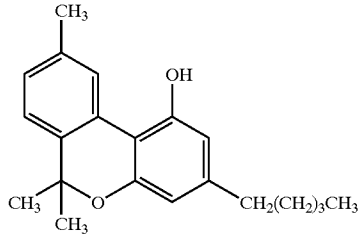
Δ^6THC (known as HU-210) is a superpotent cannabinoid receptor agonist with cannabinomimetic activity two orders of magnitude greater than the natural Δ^9 THC. The HU-210 dimethylheptyl cannabinoid, has severe side effects, including fatigue, thirst, headache, and hypotension. *J. Pharmacol. Sci.* 60:1433–1457 (1971). Subjects who received this synthetic cannabinoid with a dimethylheptyl group experienced marked psychomotor retardation, and were unwilling or incapable of assuming an erect position.

In contrast to HU-210, the (–)(3R,4R) THC-DMH enantiomer (known as HU-211) displays low affinity to the cannabinoid receptors, but retains NMDA receptor antagonist neuroprotective activity.

HU-211

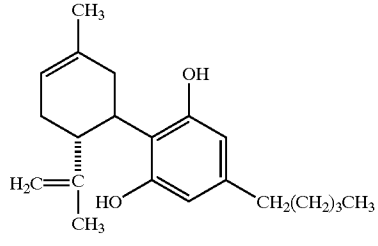


THC (tetrahydrocannabinol) is another of the cannabinoids that has been shown to be neuroprotective in cell cultures, but this protection was believed to be mediated by interaction at the cannabinoid receptor, and so would be accompanied by undesired psychotropic side effects.



THC

Although it has been unclear whether cannabimimetic activity plays a role in neuroprotection against glutamate induced neurological injury, the teaching in this field has clearly been that a cannabinoid must at least be an antagonist at the NMDA receptor to have neuroprotective effect. Hence cannabidiol (2-[3-methyl-6-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol or CBD), a cannabinoid devoid of psychoactive effect (*Pharm. Rev.* 38:21–43, 1986), has not been considered useful as a neuroprotectant. Cannabidiol has been studied as an antiepileptic (Carlini et al., *J. Clin. Pharmacol.* 21:417S–427S, 1981; Karler et al., *J. Clin. Pharmacol.* 21:437S–448S, 1981, Consroe et al., *J. Clin Phannacol.* 21:428S–436S, 1981), and has been found to lower intraocular pressure (Colasanti et al, *Exp. Eye Res.* 39:251–259, 1984 and *Gen. Pharmac.* 15:479–484, 1984).



Cannabidiol (CBD)

No signs of toxicity or serious side effects have been observed following chronic administration of cannabidiol to healthy volunteers (Cunha et al., *Pharmacology* 21:175–185, 1980), even in large acute doses of 700 mg/day (Consroe et al., *Pharmacol. Biochem. Behav.* 40:701–708, 1991) but cannabidiol is inactive at the NMDA receptor. Hence in spite of its potential use in treating glaucoma and seizures, cannabidiol has not been considered a neuroprotective agent that could be used to prevent glutamate induced damage in the central nervous system.

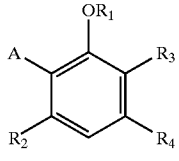
SUMMARY OF THE INVENTION

It is an object of this invention to provide a new class of antioxidant drugs, that have particular application as neuroprotectants, although they are generally useful in the treatment of many oxidation associated diseases.

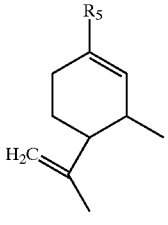
Yet another object of the invention is to provide a subset of such drugs that can be substantially free of psychoactive or psychotoxic effects, are substantially non-toxic even at very high doses, and have good tissue penetration, for example crossing the blood brain barrier.

It has surprisingly been found that cannabidiol and other cannabinoids can function as neuroprotectants, even though they lack NMDA receptor antagonist activity. This discovery was made possible because of the inventor's recognition of a previously unanticipated antioxidant property of the cannabinoids in general (and cannabidiol in particular) that functions completely independently of antagonism at the NMDA, AMPA and kainate receptors. Hence the present invention includes methods of preventing or treating diseases caused by oxidative stress, such as neuronal hypoxia, by administering a prophylactic or therapeutically effective amount of a cannabinoid to a subject who has a disease caused by oxidative stress.

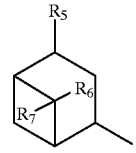
The cannabinoid may be a cannabinoid other than THC, HU-210, or other potent cannabinoid receptor agonists. The cannabinoid may also be other than HU-211 or any other NMDA receptor antagonist that has previously been reported. A potent cannabinoid receptor agonist is one that has an EC_{50} at the cannabinoid receptor of 50 nM or less, but in more particular embodiments 190 nM or 250 nM or less. In disclosed embodiments the cannabinoid is not psychoactive, and is not psychotoxic even at high doses. In some particularly disclosed embodiments, the cannabinoid is selected from the group:



where A is aryl, and particularly

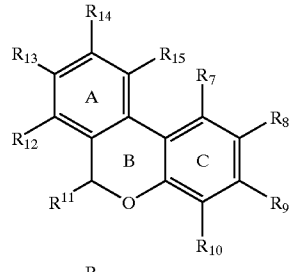


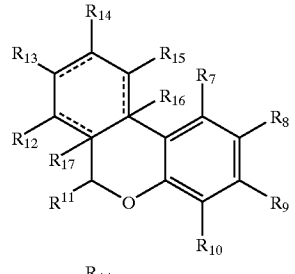
but not a pinene such as:

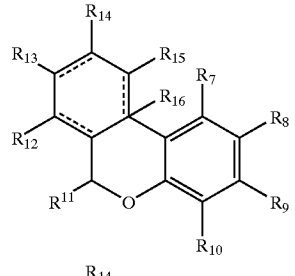


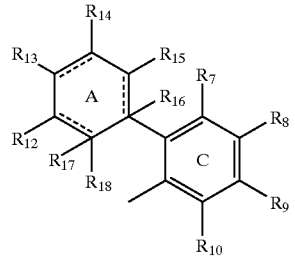
and the R_1–R_5 groups are each independently selected from the groups of hydrogen, lower substituted or unsubstituted alkyl, substituted or unsubstituted carboxyl, substituted or unsubstituted alkoxy, substituted or unsubstituted alcohol, and substituted or unsubstituted ethers, and R_6–R_7 are H or methyl. In particular embodiments, there are no nitrogens in the rings, and/or no amino substitutions on the rings.

In other embodiments, the cannabinoid is one of the following:









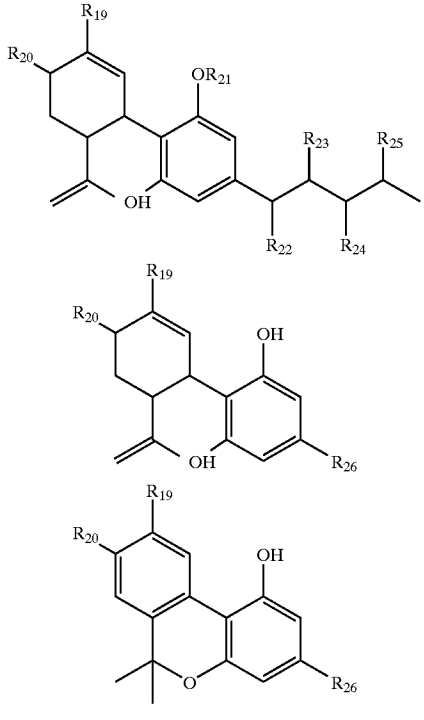
where there can be 0 to 3 double bonds on the A ring, as indicated by the optional double bonds indicated by dashed lines on the A ring. The C ring is aromatic, and the B ring can be a pyran. Particular embodiments are dibenzo pyrans and cyclohexenyl benzenediols. Particular embodiments of the cannabinoids of the present invention may also be highly lipid soluble, and in particular embodiments can be dis-

solved in an aqueous solution only sparingly (for example 10 mg/ml or less). The octanol/water partition ratio at neutral pH in useful embodiments is 5000 or greater, for example 6000 or greater. This high lipid solubility enhances penetration of the drug into the CNS, as reflected by its volume of distribution (V_d) of 1.5 L/kg or more, for example 3.5 L/kg, 7 L/kg, or ideally 10 L/kg or more, for example at least 20 L/kg. Particular embodiments may also be highly water soluble derivatives that are able to penetrate the CNS, for example carboxyl derivatives.

$R_{7\text{-}18}$ are independently selected from the group of H, substituted or unsubstituted alkyl, especially lower alkyl, for example unsubstituted C_1–C_3 alkyl, hydroxyl, alkoxy, especially lower alkoxy such as methoxy or ethoxy, substituted or unsubstituted alcohol, and unsubstituted or substituted carboxyl, for example COOH or $COCH_3$. In other embodiments $R_{7\text{-}18}$ can also be substituted or unsubstituted amino, and halogen.

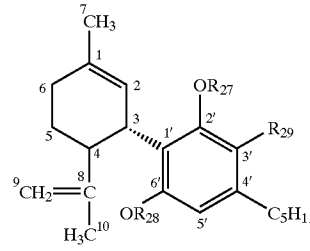
The cannabinoid has substantially no binding to the NMDAr (for example an IC_{50} greater than or equal to 5 μM or 10 μM), has substantially no psychoactive activity mediated by the cannabinoid receptor (for example an IC_{50} at the cannabinoid receptor of greater than or equal to 300 nM, for example greater than 1 μM and a K_i greater than 250 nM, especially 500–1000 nM, for example greater than 1000 nM), and antioxidant activity, as demonstratable by the Fenton reaction or cyclic voltametry.

In other particular embodiments, the cannabinoids are one of the following:

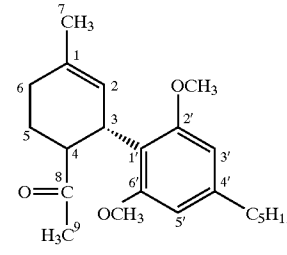


where R_{19} is substituted or unsubstituted alkyl, such as lower alkyl (for example methyl), lower alcohol (such as methyl alcohol) or carboxyl (such as carboxylic acid) and oxygen (as in =O); R_{20} is hydrogen or hydroxy; R_{21} is hydrogen, hydroxy, or methoxy; R_{22} is hydrogen or hydroxy; R_{23} is hydrogen or hydroxy; R_{24} is hydrogen or hydroxy; R_{25} is hydrogen or hydroxy; and R_{26} is substituted or unsubstituted alkyl (for example n-methyl alkyl), substituted or unsubstituted alcohol, or substituted or unsubstituted carboxy.

In yet other embodiments of the invention, the cannabinoids are

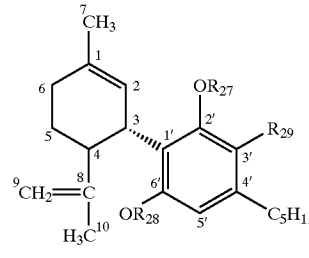


wherein numbering conventions for each of the ring positions are shown, and R_{27}, R_{28} and R_{29} are independently selected from the group consisting of H, unsubstituted lower alkyl such as CH_3, and carboxyl such as $COCH_3$. Particular examples of nonpsychoactive cannabinoids that fall within this definition are cannabidiol and



and other structural analogs of cannabidiol.

In more particular embodiments, the cannabinoid is used to prevent or treat an ischemic or neurodegenerative disease in the central nervous system of a subject, by administering to the subject a therapeutically effective amount of a cannabinoid to protect against oxidative injury to the central nervous system. The cannabinoid may be any of the compounds set forth above, or more specifically



wherein R_{27}, R_{28} and R_{29} are independently selected from the group consisting of H, lower alkyl such as CH_3, and carboxyl such as $COCH_3$, and particularly wherein

a) R_{27}=R_{28}=R_{29}=H

b) R_{27}=R_{29}=H; R_{28}=CH_3

c) R_{27}=R_{28}=CH_3; R_{29}=H

d) R_{27}=R_{28}=$COCH_3$; R_{29}=H

e) R_{27}=H; R_{28}=R_{29}=$COCH_3$

When R_{27}=R_{28}=R_{29}=H, then the compound is cannabidiol. When R_{27}=R_{29}=H and R_{28}=CH_3, the compound is CBD monomethyl ether. When R_{27}=R_{28}=CH_3 and R_{29}=H, the compound is CBD dimethyl ether. When R_{27}=R_{28}=$COCH_3$ and R_{29}=H, the compound is CBD diacetate. When R_{27}=H and R_{28}=R_{29}=$COCH_3$, the compound is CBD monoacetate. The ischemic or neurodegenerative disease may be, for

example, an ischemic infarct, Alzheimer's disease, Parkinson's disease, Down's syndrome, human immunodeficiency virus (HIV) dementia, myocardial infarction, or treatment and prevention of intraoperative or perioperative hypoxic insults that can leave persistent neurological deficits following open heart surgery requiring heart/lung bypass machines, such as coronary artery bypass grafts (CABG).

The invention also includes an assay for selecting a cannabinoid to use in treating a neurological disease by determining whether the cannabinoid is an antioxidant. Once it has been determined that the cannabinoid is an antioxidant, an antioxidant effective amount of the cannabinoid is administered to treat the neurological disease, such as a vascular ischemic event in the central nervous system, for example the type caused by a neurovascular thromboembolism. Similarly, the method of the present invention includes determining whether a disease is caused by oxidative stress, and if the disease is caused by oxidative stress, administering the cannabinoid in a therapeutically effective antioxidant amount.

The invention also includes identifying and administering antioxidant and neuroprotective compounds (such as cannabidiol) which selectively inhibit the enzyme activity of both 5- and 15-lipoxygenase more than the enzyme activity of 12-lipoxygenase. In addition, such compounds posses low NMDA antagonist activity and low cannabinoid receptor activity. Assays for selecting compounds with the desired effect on lipoxygenase enzymes, and methods for using identified compounds to treat neurological or ischemic diseases are also provided. Such diseases may include a vascular ischemic event in the central nervous system, for example a thromboembolism in the brain, or a vascular ischemic event in the myocardium. Useful administration of the compounds involves administration both during and after an ischemic injury.

These and other objects of the invention will be understood more clearly by reference to the following detailed description and drawings.

BRIEF DESCRIPTION OF THE FIGURES

FIG. **1**A is a graph showing NMDA induced cellular damage in a neuron (as measured by LDH release) in cells that were exposed to glutamate for 10 minutes, which demonstrates that increasing concentrations of cannabidiol in the cell culture protects against cellular damage.

FIG. **1**B is a graph similar to FIG. **1**A, but showing that AMPA/kainate receptor mediated damage (induced by glutamate and the AMPA/kainate receptor potentiating agents cyclothiazide or concanavalin A) is also reduced in a concentration dependent manner by the presence of cannabidiol in the culture medium.

FIG. **2**A is a bar graph showing cellular damage (as measured by LDH release) in the presence of glutamate alone (100 μM Glu), and in the presence of glutamate and 5 μM cannabidiol (CBD) or 5 μM THC, and demonstrates that CBD and THC were similarly protective.

FIG. **2**B is a bar graph similar to FIG. **2**A, but showing the cellular damage assessed in the presence of the cannabinoid receptor antagonist SR 141716A (SR), which was not found to alter the neuroprotective effect of CBD (5 μM) or THC (5 μM), indicating the effect is not a typical cannabinoid effect mediated by the cannabinoid receptor.

FIG. **3** is a graph showing the reduction oxidation potentials determined by cyclic voltametry for some natural and synthetic cannabinoids, the antioxidant BHT, and the non-cannabinoid anandamide (arachidonyl ethanolamide) which is a ligand for the cannabinoid receptor. The voltage at which initial peaks occur is an indication of antioxidant activity.

FIG. **4** is a graph that demonstrates the antioxidant properties of BHT, CBD and THC, by plotting the fluorescence of a fluorescent dye against concentrations of these substances, where declining fluorescence is an indication of greater antioxidant activity.

FIG. **5**A is a graph illustrating decreased t-butyl peroxide induced toxicity (as measured by LDH release) in the presence of increasing concentrations of cannabidiol, demonstrating that cannabidiol is an effective antioxidant in living cells.

FIG. **5**B is a bar graph comparing the antioxidant activity of several antioxidants against glutamate induced toxicity in neurons, showing that CBD has superior antioxidant activity.

FIG. **6**A is a graph showing the effect of CBD (as measured by the change in absorbance at 234 nm) on the enzymatic activity of two lipoxygenase enzymes, rabbit 15-LO and porcine 12-LO, which demonstrates that CBD inhibits 15-LO, but not 12-LO enzyme.

FIG. **6**B is a graph demonstrating that inhibitory effect of CBD on 15-LO is competitive.

FIG. **7**A is a graph similar to FIG. **6**A, but was performed in whole cells rather than purified enzyme preparations, and shows the effect of CBD (as measured by the change in absorbance at 236 nm) on the enzymatic activity of 5-LO from cultured rat basophillic leukemia cells (RBL-2H3), which demonstrates that CBD inhibits 5-LO.

FIG. **7**B is a graph showing the effect of CBD (as measured by the change in absorbance at 236 nm) on the formation of 12-HETE (the product of 12-LO) by human leukocytes (12-LO type 1).

FIG. **7**C is a graph similar to FIG. **7**B, showing the effect of CBD (as measured by the change in absorbance at 236 nm) on the formation of 12-HETE by human platelets (12-LO type 2).

FIG. **8** is a bar graph demonstrating that 12-HETE can protect cortical neurons from NMDAr toxicity most effectively when administered during and post ischemia.

DETAILED DESCRIPTION OF SOME SPECIFIC EMBODIMENTS

This invention provides antioxidant compounds and compositions, such as pharmaceutical compositions, that include cannabinoids that act as free radical scavengers for use in prophylaxis and treatment of disease. The invention also includes methods for using the antioxidants in prevention and treatment of pathological conditions such as ischemia (tissue hypoxia), and in subjects who have been exposed to oxidant inducing agents such as cancer chemotherapy, toxins, radiation, or other sources of oxidative stress. The compositions and methods described herein are also used for preventing oxidative damage in transplanted organs, for inhibiting reoxygenation injury following reperfusion of ischemic tissues (for example in heart disease), and for any other condition that is mediated by oxidative or free radical mechanisms of injury. In particular embodiments of the invention, the compounds and compositions are used in the treatment of ischemic cardiovascular and neurovascular conditions, and neurodegenerative diseases. However the present invention can also be used as an antioxidant treatment in non-neurological diseases.

Molecular oxygen is essential for aerobic organisms, where it participates in many biochemical reactions, includ-

ing its role as the terminal electron acceptor in oxidative phosphorylation. However excessive concentrations of various forms of reactive oxygen species and other free radicals can have serious adverse biological consequences, including the peroxidation of membrane lipids, hydroxylation of nucleic acid bases, and the oxidation of sulfhydryl groups and other protein moieties. Biological antioxidants include tocopherols and tocotrieneols, carotenoids, quinones, bilirubin, ascorbic acid, uric acid, and metal binding proteins. However these endogenous antioxidant systems are often overwhelmed by pathological processes that allow permanent oxidative damage to occur to tissue.

Free radicals are atoms, ions or molecules that contain an unpaired electron, are usually unstable, and exhibit short half-lives. Reactive oxygen species (ROS) is a collective term, designating the oxygen radicals (e.g. $.O_2^-$ superoxide radical), which by sequential univalent reduction produces hydrogen peroxide (H_2O_2) and hydroxyl radical (.OH). The hydroxyl radical sets off chain reactions and can interact with nucleic acids. Other ROS include nitric oxide (NO.) and peroxy nitrite (NOO.), and other peroxyl (RO_2.) and alkoxyl (RO.) radicals. Increased production of these poisonous metabolites in certain pathological conditions is believed to cause cellular damage through the action of the highly reactive molecules on proteins, lipids and DNA. In particular, ROS are believed to accumulate when tissues are subjected to ischemia, particularly when followed by reperfusion.

The pharmaceutical compositions of the present invention have potent antioxidant and/or free radical scavenging properties, that prevent or reduce oxidative damage in biological systems, such as occurs in ischemic/reperfusion injury, or in chronic neurodegenerative diseases such as Alzheimer's disease, HIV dementia, and many other oxidation associated diseases.

DEFINITIONS

"Oxidative associated diseases" refers to pathological conditions that result at least in part from the production of or exposure to free radicals, particularly oxyradicals, or reactive oxygen species. It is evident to those of skill in the art that most pathological conditions are multifactorial, and that assigning or identifying the predominant causal factors for any particular condition is frequently difficult. For these reasons, the term "free radical associated disease" encompasses pathological states that are recognized as conditions in which free radicals or ROS contribute to the pathology of the disease, or wherein administration of a free radical inhibitor (e.g. desferroxamine), scavenger (e.g. tocopherol, glutathione) or catalyst (e.g. superoxide dismutase, catalase) is shown to produce detectable benefit by decreasing symptoms, increasing survival, or providing other detectable clinical benefits in treating or preventing the pathological state.

Oxidative associated diseases include, without limitation, free radical associated diseases, such as ischemia, ischemic reperfusion injury, inflammatory diseases, systemic lupus erythematosis, myocardial ischemia or infarction, cerebrovascular accidents (such as a thromboembolic or hemorrhagic stroke) that can lead to ischemia or an infarct in the brain, operative ischemia, traumatic hemorrhage (for example a hypovolemic stroke that can lead to CNS hypoxia or anoxia), spinal cord trauma, Down's syndrome, Crohn's disease, autoimmune diseases (e.g. rheumatoid arthritis or diabetes), cataract formation, uveitis, emphysema, gastric ulcers, oxygen toxicity, neoplasia, undesired cellular apoptosis, radiation sickness, and others. The present invention is believed to be particularly beneficial in the treatment of oxidative associated diseases of the CNS, because of the ability of the cannabinoids to cross the blood brain barrier and exert their antioxidant effects in the brain. In particular embodiments, the pharmaceutical composition of the present invention is used for preventing, arresting, or treating neurological damage in Parkinson's disease, Alzheimer's disease and HIV dementia; autoimmune neurodegeneration of the type that can occur in encephalitis, and hypoxic or anoxic neuronal damage that can result from apnea, respiratory arrest or cardiac arrest, and anoxia caused by drowning, brain surgery or trauma (such as concussion or spinal cord shock).

As used herein, an "antioxidant" is a substance that, when present in a mixture containing an oxidizable substrate biological molecule, significantly delays or prevents oxidation of the substrate biological molecule. Antioxidants can act by scavenging biologically important reactive free radicals or other reactive oxygen species ($.O_2^-$, H_2O_2, .OH, HOCl, ferryl, peroxyl, peroxynitrite, and alkoxyl), or by preventing their formation, or by catalytically converting the free radical or other reactive oxygen species to a less reactive species. Relative antioxidant activity can be measured by cyclic voltametry studies of the type disclosed in Example 5 (and FIG. **3**), where the voltage (x-axis) is an index of relative antioxidant activity. The voltage at which the first peak occurs is an indication of the voltage at which an electron is donated, which in turn is an index of antioxidant activity.

"Therapeutically effective antioxidant doses" can be determined by various methods, including generating an empirical dose-response curve, predicting potency and efficacy of a congener by using quantitative structure activity relationships (QSAR) methods or molecular modeling, and other methods used in the pharmaceutical sciences. Since oxidative damage is generally cumulative, there is no minimum threshold level (or dose) with respect to efficacy. However, minimum doses for producing a detectable therapeutic or prophylactic effect for particular disease states can be established.

As used herein, a "cannabinoid" is a chemical compound (such as cannabinol, THC or cannabidiol) that is found in the plant species *Cannabis saliva* (marijuana), and metabolites and synthetic analogues thereof that may or may not have psychoactive properties. Cannabinoids therefore include (without limitation) compounds (such as THC) that have high affinity for the cannabinoid receptor (for example K_i<250 nM), and compounds that do not have significant affinity for the cannabinoid receptor (such as cannabidiol, CBD). Cannabinoids also include compounds that have a characteristic dibenzopyran ring structure (of the type seen in THC) and cannabinoids which do not possess a pyran ring (such as cannabidiol). Hence a partial list of cannabinoids includes THC, CBD, dimethyl heptylpentyl cannabidiol (DMHP-CBD), 6,12-dihydro-6-hydroxy-cannabidiol (described in U.S. Pat. No. 5,227,537, incorporated by reference); (3S,4R)-7-hydroxy-Δ^6-tetrahydrocannabinol homologs and derivatives described in U.S. Pat. No. 4,876,276, incorporated by reference; (+)-4-[4-DMH-2,6-diacetoxy-phenyl]-2-carboxy-6,6-dimethylbicyclo[3.1.1]hept-2-en, and other 4-phenylpinene derivatives disclosed in U.S. Pat. No. 5,434,295, which is incorporated by reference; and cannabidiol (−)(CBD) analogs such as (−)CBD-monomethylether, (−)CBD dimethyl ether; (−)CBD diacetate; (−)3'-acetyl-CBD monoacetate; and ±AF11, all of which are disclosed in Consroe et al., *J. Clin. Phannacol.*

21:428S–436S, 1981, which is also incorporated by reference. Many other cannabinoids are similarly disclosed in Agurell et al., *Pharmacol. Rev.* 38:31–43, 1986, which is also incorporated by reference.

As referred to herein, the term "psychoactivity" means "cannabinoid receptor mediated psychoactivity." Such effects include, euphoria, lightheadedness, reduced motor coordination, and memory impairment. Psychoactivity is not meant to include non-cannabinoid receptor mediated effects such as the anxiolytic effect of CBD.

The "lipoxygenase enzyme activity" refers to the relative level of lipoxygenase enzyme activity for a particular lipoxgenase, such as 5-, 15- or 12-lipoxygenase, as measured in Example 8. A compound would be said to "selectively inhibit a lipoxgenase enzyme" if the concentration of inhibitor required to reduce enzyme activity by 50% was at least about 5 times less than the amount required to reduce activity of a second lipoxgenase enzyme by the same degree (under the same conditions, i.e. temperature, substrate concentration, etc.)

An "antagonist" is a compound that binds and occupies a receptor without activating it. In the presence of a sufficient concentration of antagonist, an agonist cannot activate its receptor. Therefore, antagonists may decrease the neurotoxicity mediated by NMDA (as described in Example 3) or AMPA and Kainate (as described in Example 4).

An "agonist" is a compound that activates a receptor. When the receptor is activated for a longer than normal period of time, this may cause neurotoxicity, as in the case of NMDA, AMPA and kainate receptors (see Examples 3 and 4).

The term "alkyl" refers to a cyclic, branched, or straight chain alkyl group containing only carbon and hydrogen, and unless otherwise mentioned contains one to twelve carbon atoms. This term is further exemplified by groups such as methyl, ethyl, n-propyl, isobutyl, t-butyl, pentyl, pivalyl, heptyl, adamantyl, and cyclopentyl. Alkyl groups can either be unsubstituted or substituted with one or more substituents, e.g. halogen, alkyl, alkoxy, alkylthio, trifluoromethyl, acyloxy, hydroxy, mercapto, carboxy, aryloxy, aryloxy, aryl, arylalkyl, heteroaryl, amino, alkylamino, dialkylamino, morpholino, piperidino, pyrrolidin-1-yl, piperazin-1-yl, or other functionality.

The term "lower alkyl" refers to a cyclic, branched or straight chain monovalent alkyl radical of one to seven carbon atoms. This term is further exemplified by such radicals as methyl, ethyl, n-propyl, i-propyl, n-butyl, t-butyl, i-butyl (or 2-methylpropyl), cyclopropylmethyl, i-amyl, n-amyl, hexyl and heptyl. Lower alkyl groups can also be unsubstituted or substituted, where a specific example of a substituted alkyl is 1,1-dimethyl heptyl.

"Hydroxyl" refers to —OH.

"Alcohol" refers to R—OH, wherein R is alkyl, especially lower alkyl (for example in methyl, ethyl or propyl alcohol). An alcohol may be either linear or branched, such as isopropyl alcohol.

"Carboxyl" refers to the radical —COOH, and substituted carboxyl refers to —COR where R is alkyl, lower alkyl or a carboxylic acid or ester.

The term "aryl" or "Ar" refers to a monovalent unsaturated aromatic carbocyclic group having a single ring (e.g. phenyl) or multiple condensed rings (e.g. naphthyl or anthryl), which can optionally be unsubstituted or substituted with, e.g., halogen, alkyl, alkoxy, alkylthio, trifluoromethyl, acyloxy, hydroxy, mercapto, carboxy, aryloxy, aryl, arylalkyl, heteroaryl, amino, alkylamino, dialkylamino, morpholino, piperidino, pyrrolidin-1-yl, piperazin-1-yl, or other functionality.

The term "alkoxy" refers to a substituted or unsubstituted alkoxy, where an alkoxy has the structure —O—R, where R is substituted or unsubstituted alkyl. In an unsubstituted alkoxy, the R is an unsubstituted alkyl. The term "substituted alkoxy" refers to a group having the structure —O—R, where R is alkyl which is substituted with a non-interfering substituent. The term "arylalkoxy" refers to a group having the structure —O—R—Ar, where R is alkyl and Ar is an aromatic substituent. Arylalkoxys are a subset of substituted alkoxys. Examples of useful substituted alkoxy groups are: benzyloxy, naphthyloxy, and chlorobenzyloxy.

The term "aryloxy" refers to a group having the structure —O—Ar, where Ar is an aromatic group. A particular aryloxy group is phenoxy.

The term "heterocycle" refers to a monovalent saturated, unsaturated, or aromatic carbocyclic group having a single ring (e.g. morpholino, pyridyl or faryl) or multiple condensed rings (e.g. indolizinyl or benzo[b]thienyl) and having at least one heteroatom, defined as N, O, P, or S, within the ring, which can optionally be unsubstituted or substituted with, e.g. halogen, alkyl, alkoxy, alkylthio, trifluoromethyl, acyloxy, hydroxy, mercapto, carboxy, aryloxy, aryl, arylakyl, heteroaryl, amino, alkylamino, dialkylamino, morpholino, piperidino, pyrrolidin-1-yl, piperazin-1-yl, or other functionality.

"Arylalkyl" refers to the groups —R—Ar and —R—HetAr, where Ar is an aryl group. HetAr is a heteroaryl group, and R is a straight-chain or branched chain aliphatic group. Example of arylaklyl groups include benzyl and furfuryl. Arylalkyl groups can optionally be unsubstituted or substituted with, e.g., halogen, alkyl, alkoxy, alkylthio, trifluoromethyl, acyloxy, hydroxy, mercapto, carboxy, aryloxy, aryl, arylalkyl, heteroaryl, amino, alkylamino, dialkylamino, morpholino, peperidino, pyrrolidin-1-yl, piperazin-1-yl, or other functionality.

The term "halo" or "halide" refers to fluoro, bromo, chloro and iodo substituents.

The term "amino" refers to a chemical functionality —NR'R" where R' and R" are independently hydrogen, alkyl, or aryl. The term "quaternary amine" refers to the positively charged group —N^+R'R", where R'R" and R" are independently selected and are alkyl or aryl. A particular amino group is —NH_2.

A "pharmaceutical agent" or "drug" refers to a chemical compound or composition capable of inducing a desired therapeutic or prophylactic effect when properly administered to a subject.

All chemical compounds include both the (+) and (−) stereoisomers, as well as either the (+) or (−) stereoisomer.

Other chemistry terms herein are used according to conventional usage in the art, as exemplified by *The McGraw-Hill Dictionary of Chemical Terms* (1985) and *The Condensed Chemical Dictionary* (1981).

The following examples show that both nonpsychoactive cannabidiol, and psychoactive cannabinoids such as THC, can protect neurons from glutamate induced death, by a mechanism independent of cannabinoid receptors. Cannabinoids are also be shown to be potent antioxidants capable of preventing ROS toxicity in neurons.

EXAMPLE 1

Preparation of Cannabinoids and Neuronal Cultures

Cannabidiol, THC and reactants other than those specifically listed below were purchased from Sigma Chemical,

Co. (St. Louis, Mo.). Cyclothiazide, glutamatergic ligands and MK-801 were obtained from Tocris Cookson (UK). Dihydrorhodamine was supplied by Molecular Probes (Eugene, Oreg.). T-butyl hydroperoxide, tetraethylammonium chloride, ferric citrate and sodium dithionite were all purchased from Aldrich (WI). All culture media were Gibco/BRL (MD) products.

Solutions of cannabinoids, cyclothiazide and other lipophiles were prepared by evaporating a 10 mM ethanolic solution (under a stream of nitrogen) in a siliconized microcentrifuge tube. Dimethyl sulfoxide (DMSO, less than 0.05% of final volume) was added to ethanol to prevent the lipophile completely drying onto the tube wall. After evaporation, 1 ml of culture media was added and the drug was dispersed using a high power sonic probe. Special attention was used to ensure the solution did not overheat or generate foam. Following dispersal, all solutions were made up to their final volume in siliconized glass tubes by mixing with an appropriate quantity of culture media.

Primary neuronal cultures were prepared according to the method of Ventra et al. (J. Neurochem. 66:1752–1761, 1996). Fetuses were extracted by Cesarian section from a 17 day pregnant Wistar rat, and the feral brains were placed into phosphate buffered saline. The cortices were then dissected out, cut into small pieces and incubated with papain for nine minutes at 37° C. After this time the tissue was dissociated by passage through a fire polished Pasteur pipette, and the resultant cell suspension separated by centrifugation over a gradient consisting of 10 mg/ml bovine serum albumin and 10 mg/ml ovomucoid (a trypsin inhibitor) in Earls buffered salt solution. The pellet was then re-suspended in high glucose, phenol red free Dulbeco's modified Eagles medium containing 10% fetal bovine serum, 2 mM glutamine, 100 IU penicillin, and 100 μg/ml streptomycin (DMEM). Cells were counted, tested for vitality using the trypan blue exclusion test and seeded onto poly-D-lysine coated 24 multiwell plates. After 96 hours, 10 μM fluoro-deoxyuridine and 10 μM uridine were added to block glial cell growth. This protocol resulted in a highly neuron-enriched culture.

EXAMPLE 2

Preparation of Astrocytes and Conditioned Media

Astrocyte conditioned DMEM was used throughout the AMPA/kainate toxicity procedure and following glutamate exposure in the NMDAr mediated toxicity protocol. Media was conditioned by 24 hour treatment over a confluent layer of type I astrocytes, prepared from two day old Wistar rat pups. Cortices were dissected, cut into small pieces, and enzymatically digested with 0.25% trypsin. Tissue was then dissociated by passage through a fire polished Pasteur pipette and the cell suspension plated into untreated 75 cm^2 T-flasks. After 24 hours the media was replaced and unattached cells removed. Once astrocytes achieved confluence, cells were divided into four flasks. Media for experiments was conditioned by a 24 hour exposure to these astrocytes, after which time it was frozen at −20° C. until use. Astrocyte cultures were used to condition DMEM for no longer than two months.

EXAMPLE 3

NMDA Mediated Toxicity Studies

Glutamate neurotoxicity can be mediated by NMDA, AMPA or kainate receptors. To examine NMDAr mediated toxicity, cultured neurons (cultured for 14–18 days) were exposed to 250 μM glutamate for 10 minutes in a magnesium free saline solution. The saline was composed of 125 mM NaCl, 25 mM glucose, 10 mM HEPES (pH 7.4), 5 mM KCl, 1.8 mM calcium chloride and 5% bovine serum albumin. Following exposure, cells were washed twice with saline, and incubated for 18 hours in conditioned DMEM. The level of lactate dehydrogenase (LDH) in the media was used as an index of cell injury.

Toxicity was completely prevented by addition of the NMDAr antagonist, MK-801 (500 nM, data not shown). However, FIG. **1**A shows that cannabidiol also prevented neurotoxicity (maximum protection 88±9%) with an EC_{50} of 2–4 μM (specifically about 3.5 μM).

EXAMPLE 4

AMPA and Kainate Receptor Mediated Toxicity Studies

Unlike NMDA receptors, which are regulated by magnesium ions, AMPA/kainate receptors rapidly desensitize following ligand binding. To examine AMPA and kainate receptor mediated toxicity, neurons were cultured for 7–13 days, then exposed to 100 μM glutamate and 50 μM cyclothiazide (used to prevent AMPA receptor desensitization). Cells were incubated with glutamate in the presence of 500 nM MK-801 (an NMDAr antagonist) for 18–20 hours prior to analysis. Specific AMPA and kainate receptor ligands were also used to separately examine the effects of cannabinoids on AMPA and kainate receptor mediated events. Fluorowillardiine (1.5 μM) was the AMPA agonist and 4-methyl glutamate (10 μM) was the kainate agonist used to investigate receptor mediated toxicity. When specifically examining kainate receptor activity, cyclothiazide was replaced with 0.15 mg/ml Concanavalin-A.

Cannabidiol protection against AMPA/kainate mediated neurotoxicity is illustrated in FIG. **1**B, where LDH in the media was used as an index of cell injury. The neuroprotective effect of cannabidiol was similar to that observed in the NMDA mediated toxicity model (FIG. **1**A). Cannabidiol prevented neurotoxicity (maximum protection 80±17%) with an EC_{50} of 2–4 μM (specifically about 3.3 μM). Comparable results were obtained with either the AMPA receptor ligand, fluorowillardiine or the kainate receptor specific ligand, 4-methyl-glutamate (data not shown). Hence cannabidiol protects similarly against toxicity mediated by NMDA, AMPA or kainate receptors.

Unlike cannabidiol, THC is a ligand (and agonist) for the brain cannabinoid receptor. The action of THC at the cannabinoid receptor has been proposed to explain the ability of THC to protect neurons from NMDAr toxicity in vitro. However in AMPA/kainate receptor toxicity assays, THC and cannabidiol were similarly protective (FIG. **2**A), indicating that cannabinoid neuroprotection is independent of cannabinoid receptor activation. This was confirmed by inclusion of cannabinoid receptor antagonist SR-141716A in the culture media (SR in FIG. **2**B). See Mansbach et al., *Psychopharmacology* 124:315–22, 1996, for a description of SR-141716A. Neither THC nor cannabidiol neuroprotection was affected by cannabinoid receptor antagonist (FIG. **2**B).

EXAMPLE 5

Cyclic Voltametery Studies or ReDox Potentials

To investigate whether cannabinoids protect neurons against glutamate damage by reacting with ROS, the anti-

oxidant properties of cannabidiol and other cannabinoids were assessed. Cyclic voltametry, a procedure that measures the ability of a compound to accept or donate electrons under a variable voltage potential, was used to measure the oxidation potentials of several natural and synthetic cannabinoids. These studies were performed with an EG&G Princeton Applied Research potentiostat/galvanostat (Model 273/PAR 270 software, NJ). The working electrode was a glassy carbon disk with a platinum counter electrode and silver/silver chloride reference. Tetraethylammonium chloride in acetonitrile (0.1 M) was used as an electrolyte. Cyclic voltametry scans were done from +0 to 1.8 V at scan rate of 100 mV per second. The reducing ability of cannabidiol (CBD), THC, HU-211, and BHT were measured in this fashion. Anandamide, a cannabinoid receptor ligand without a cannabinoid like structure, was used as a non-responsive control. Each experiment was repeated twice with essentially the same results.

Cannabidiol, THC and the synthetic cannabinoid HU-211 all donated electrons at a similar potential as the antioxidant BHT. Anandamide (arachidonyl ethanolamide) did not undergo oxidation at these potentials (FIG. **3**). Several other natural and synthetic cannabinoids, including cannabidiol, nabilone, and levanantrodol were also tested, and they too exhibited oxidation profiles similar to cannabidiol and THC (data not shown).

EXAMPLE 6

Iron Catalyzed Dihydrorhodamine Oxidation (Fenton Reaction)

The ability of cannabinoids to be readily oxidized, as illustrated in Example 5, indicated they possess antioxidant properties comparable to BHT. The antioxidant activity of BHT was examined in a Fenton reaction, in which iron is catalyzed to produce ROS. Cannabidiol (CBD) and tetrahydrocannabinol (THC) were evaluated for their ability to prevent oxidation of dihydrorhodamine to the fluorescent compound rhodamine. Oxidant was generated by ferrous catalysis (diothionite reduced ferric citrate) of t-butyl hydroperoxide in a 50:50 water:acetonitrile (v/v) solution. Dihydrorhodamine (50 μM) was incubated with 300 μM t-butyl hydroperoxide and 0.5 μM iron for 5 minutes. After this time, oxidation was assessed by spectrofluorimetry (Excit=500 nm, Emiss=570 nm). Various concentrations of cannabinoids and BHT were included to examine their ability to prevent dihydrorhodiamine oxidation.

Cannabidiol, THC and BHT all prevented dihydrorhodamine oxidation in a similar, concentration dependent manner (FIG. **4**), indicating that cannabinoids have antioxidant potency comparable to BHT.

To confirm that cannabinoids act as antioxidants in the intact cell, neurons were also incubated with the oxidant t-butyl hydroperoxide and varying concentrations of cannabidiol (FIG. **5**A). The t-butyl hydroperoxide oxidant was chosen for its solubility in both aqueous and organic solvents, which facilitates oxidation in both cytosolic and membrane cell compartments. Cell toxicity was assessed 18–20 hours after insult by measuring lactate dehydrogenase (LDH) release into the culture media. All experiments were conducted with triple or quadruple values at each point and all plates contained positive (glutamate alone) and baseline controls. The assay was validated by comparison with an XTT based metabolic activity assay. As shown in FIG. **5**A, cannabidiol protected neurons against ROS toxicity in a dose related manner, with an EC_{50} of about 6 μM. The maximum protection observed was 88±9%.

Cannabidiol was also compared with known antioxidants in an AMPA/kainate toxicity protocol. Neurons were exposed to 100 μM glutamate and equimolar (5 μM) cannabidiol, α-tocopherol, BHT or ascorbate (FIG. **5**B). Although all of the antioxidants attenuated glutamate toxicity, cannabidiol was significantly more protective than either α-tocopherol or ascorbate. The similar antioxidant abilities of cannabidiol and BHT in this chemical system (FIG. **4**), and their comparable protection in neuronal cultures (FIG. **5**B), implies that cannabidiol neuroprotection is due to an antioxidant effect.

EXAMPLE 7

In vivo Rat Studies

The middle cerebral artery of chloral hydrate anesthetized rats was occluded by insertion of suture thread into it. The animals were allowed to recover from the anesthetic and move freely for a period of two hours. After this time the suture was removed under mild anesthetic and the animals allowed to recover for 48 hours. Then the animals were tested for neurological deficits, sacrificed, and the infarct volume calculated. To examine the infarct volume, animals were anesthetized, ex-sanguinated, and a metabolically active dye (3-phenyl tetrazolium chloride) was pumped throughout the body. All living tissues were stained pink by the dye, while morbid regions of infarcted tissue remained white. Brains were then fixed for 24 hours in formaldehyde, sliced and the infarct volumes measured.

One hour prior to induction of ischemia 20 mg/kg of cannabidiol was administered by intra-peritoneal injection (ip) in a 90% saline:5% emulphor 620 (emulsifier):5% ethanol vehicle. A second ip 10 mg/kg dose of cannabidiol was administered 8 hours later using the same vehicle. Control animals received injections of vehicle without drug. IV doses would be expected to be 3–5 times less because of reduction of first pass metabolism.

The infarct size and neurological assessment of the test animals is shown Table 1.

TABLE 1

Cannabidiol protects rat brains from ischemia damage

	Volume of Infarct (mm3)		Behavioral Deficit Score	
Animal	Drug	Control	Drug	Control
1	108.2	110.5	3	2
2	83.85	119.6	4	4
3	8.41	118.9	3	4
4	75.5	177.7	1	4
5	60.53	33.89	1	3
6	27.52	255.5	1	5
7	23.16	143	1	4
Mean	55.3	137.0	2.0	3.7
SEM	13.8	25.7	0.5	0.4
	p = 0.016 significant		p = 0.015 significant	

*Neurological scoring is performed on a subjective 1–5 scale of impairment. 0 = no impairment, 5 = severe (paralysis)

This data shows that infarct size was approximately halved in the animals treated with cannabidiol, which was also accompanied by a substantial improvement in the neurological status of the animal.

These studies with the nonpsychotropic marijuana constituent, cannabidiol, demonstrate that protection can be achieved against both glutamate neurotoxicity and free radical induced cell death. THC, the psychoactive principle

of cannabis, also blocked glutamate neurotoxicity with a potency similar to cannabidiol. In both cases, neuroprotection is unaffected by the presence of a cannabinoid receptor antagonist. These results therefore surprisingly demonstrate that cannabinoids can have useful therapeutic effects that are not mediated by cannabinoid receptors, and therefore are not necessarily accompanied by psychoactive side effects. Cannabidiol also acts as an anti-epileptic and anxiolytic, which makes it particularly useful in the treatment of neurological diseases in which neuroanatomic defects can predispose to seizures (e.g. subarachnoid hemorrhage).

A particular advantage of the cannabinoid compounds of the present invention is that they are highly lipophilic, and have good penetration into the central nervous system. The volume of distribution of some of these compounds is at least 100 L in a 70 kg person (1.4 L/kg), more particularly at least 250 L, and most particularly 500 L or even 700 L in a 70 kg person (10 L/kg). The lipophilicity of particular compounds is also about as great as that of THC, cannabidiol or other compounds that have excellent penetration into the brain and other portions of the CNS.

Cannabinoids that lack psychoactivity or psychotoxicity are particularly useful embodiments of the present invention, because the absence of such side effects allows very high doses of the drug to be used without encountering unpleasant side effects (such as dysphoria) or dangerous complications (such as obtundation in a patient who may already have an altered mental status). For example, therapeutic antioxidant blood levels of cannabidiol can be 5–20 mg/kg, without significant toxicity, while blood levels of psychoactive cannabinoids at this level would produce obtundation, headache, conjunctival irritation, and other problems. Particular examples of the compounds of the present invention have low affinity to the cannabinoid receptor, for example a K_i of greater than 250 nM, for example $K_i \geqq 500$–1000 nM. A compound with a $K_i \geqq 1000$ nM is particularly useful, which compound has essentially no psychoactivity mediated by the cannabinoid receptor.

Cannabidiol blocks glutamate toxicity with equal potency regardless of whether the insult is mediated by NMDA, AMPA or kainate receptors. Cannabidiol and THC have been shown to be comparable to the antioxidant BHT, both in their ability to prevent dihydrorhodamine oxidation and in their cyclic voltametric profiles. Several synthetic cannabinoids also exhibited profiles similar to the BHT, although anandamide, which is not structurally related to cannabinoids, did not. These findings indicate that cannabinoids act as antioxidants in a non-biological situation, which was confirmed in living cells by showing that cannabidiol attenuates hydroperoxide induced neurotoxicity. The potency of cannabidiol as an antioxidant was examined by comparing it on an equimolar basis with three other commonly used compounds.

In the AMPA/kainate receptor dependent neurotoxicity model, cannabidiol neuroprotection was comparable to the potent antioxidant, BHT, but significantly greater than that observed with either α-tocopherol or ascorbate. This unexpected superior antioxidant activity (in the absence of BHT tumor promoting activity) shows for the first time that cannabidiol, and other cannabinoids, can be used as antioxidant drugs in the treatment (including prophylaxis) of oxidation associated diseases, and is particularly useful as a neuroprotectant. The therapeutic potential of nonpsychoactive cannabinoids is particularly promising, because of the absence of psychotoxicity, and the ability to administer higher doses than with psychotropic cannabinoids, such as THC. Previous studies have also indicated that cannabidiol is not toxic, even when chronically administered to humans or given in large acute doses (700 mg/day).

EXAMPLE 8

Effect of Cannabidiol on Lipoxygenase Enzymes

This example describes in vitro and in vivo assays to examine the effect of cannabidiol (CBD) on three lipoxygenase (LO) enzymes: 5-LO, 12-LO and 15-LO.

In vitro Enzyme Assay

The ability of CBD to inhibit lipoxygenase was examined by measuring the time dependent change in absorption at 234 nM following addition of 5 U of each lipoxygenase (rabbit 15-LO purchased from Biomol (PA), porcine 12-LO purchased from Cayman chemicals (MI)) to a solution containing 10 μM (final concentration) linoleic acid.

Enzyme studies were performed using a u.v. spectrophotometer and a 3 ml quartz cuvette containing 2.5 ml of a stirred solution of 12.5 μM sodium linoleic acid (sodium salt) in solution A (25 mM Tris (pH 8.1), 1 mM EDTA 0.1% methyl cellulose). The reaction was initiated by addition of 0.5 ml enzyme solution (10 U/ml enzyme in solution A) and recorded for 60 seconds. Lipoxygenase exhibits non-Michaelis-Menten kinetics, an initial "lag" (priming) phase followed by a linear phase which is terminated by product inhibition. These complications were reduced by assessing enzyme activity (change in absorption) over the "steepest" 20 second period in a 60 second run time. Recordings examined the absorption at 234 nm minus the value at a reference wavelength of 280 nm. Linoleic acid was used as the substrate rather than arachidonic acid, because the products are less inhibitory to the enzyme, thereby providing a longer "linear phase".

Cell Purification and Separation

Human platelets and leukocytes were purified from buffy coat preparations (NIH Blood Bank) using a standard Ficoll based centrifugation method used in blood banks. Prior to use, cells were washed three times to eliminate contaminating cell types. Cultured rat basophillic leukemia cells (RBL-2H3) were used as a source of 5-lipoxygenase.

In vivo Determination of Lipoxygenase Activity

Cells were incubated with arachidonic acid and stimulated with the calcium ionophore A23187. Lipids were extracted and separated by reverse phase HPLC. Product formation was assessed as the area of a peak that co-eluted with an authentic standard, had a greater absorbance at 236 nm than at either 210 or 280 nm, and the formation of which was inhibited by a lipoxygenase inhibitor.

Cell pellets were triturated in DMEM culture media, aliquoted and pre-incubated for 15 minutes with 20 μM arachidonic acid and varying concentrations of cannabidiol and/or 40 μM nordihydroguaiaretic acid (a lipxygenase inhibitor). Platelets and leukocytes were also pre-incubated with 80 μM manoalide (Biomol) to prevent phospholipase A2 activation. Product formation was initiated by addition of 5 μM A23187 and incubation for 10 minutes at 37° C. At the end of the incubation, the reaction was stopped by addition of 15% 1M HCl and 10 ng/ml prostaglandin B2 (internal standard). Lipids were extracted with 1 volume of ethyl ether, which was dried under a stream of nitrogen. Samples were reconstituted in 50% acetonitrile:50% H_2O and separated by reverse phase HPLC using a gradient running from 63% acetonitrile: 37% H_2O:0.2% acetic acid to 90% acetonitrile (0.2% acetic acid) over 13 minutes.

Measurement of NMDAr Toxicity

The ability of 12-HETE (12-(s)-hydroxy-eicosatetraenoic acid, the product of the action of 12-lipoxygenase on arachi-

donic (eicosatetraenoic) acid) to protect cortical neurons from NMDAr toxicity was measured as described in Example 3. The 12-HETE (0.5 μg/ml) was added either during ischemia (co-incubated with the glutamate), during post-ischemia (co-incubated with the DMEM after washing the cells), or during both ischemia and post-ischemia.

Results

Using semi-purified enzyme preparations, the effect of CBD on rabbit 15-LO and porcine 12-LO was compared. As shown in FIGS. **6**A and B, CBD is a potent competitive inhibitor of 15-LO with an EC_{50} of 598 nM. However, CBD had no effect on the 12-LO enzyme.

Using whole cell preparations, the effect of CBD on 5- and 12-LO enzymes was investigated. As shown in FIG. **7**A, CBD inhibited 5-LO in cultured rat basophillic leukemia cells (RBL-2H3) with an EC_{50} of 1.92 μM. However, CBD had no effect on 12-LO, as monitored by the production of 12-HETE (the product of 12-LO), in either human leukocytes or platelets (FIGS. **7**B and C). The leukocyte 12-LO is similar, while the platelet 12-LO is structurally and functionally different, from the porcine 12-LO used in the in vitro enzyme study.

The ability of 12-HETE to protect cortical neurons from NMDAr toxicity is shown in FIG. **8**. To achieve best protection from NMDAr toxicity, 12-HETE was administered both during and post ischemia.

Therefore, CBD serves as a selective inhibitor of at least two lipoxygenase enzymes, 5-LO and 15-LO, but had no effect on 12-LO. Importantly, this is the first demonstration (FIG. **8**) that the 12-LO product 12-HETE can play a significant role in protecting neurons from NMDAr mediated toxicity. Although the mechanism of this protection is unknown at the present time, 12-HETE is known to be an important neuromodulator, due to its ability to influence potassium channel activity.

EXAMPLE 9

Methods of Treatment

The present invention includes a treatment that inhibits oxidation associated diseases in a subject such as an animal, for example a rat or human. The method includes administering the antioxidant drugs of the present invention, or a combination of the antioxidant drug and one or more other pharmaceutical agents, to the subject in a pharmaceutically compatible carrier and in an effective amount to inhibit the development or progression of oxidation associated diseases. Although the treatment can be used prophylactically in any patient in a demographic group at significant risk for such diseases, subjects can also be selected using more specific criteria, such as a definitive diagnosis of the condition. The administration of any exogenous antioxidant cannabinoid would inhibit the progression of the oxidation associated disease as compared to a subject to whom the cannabinoid was not administered. The antioxidant effect, however, increases with the dose of the cannabinoid.

The vehicle in which the drug is delivered can include pharmaceutically acceptable compositions of the drugs of the present invention using methods well known to those with skill in the art. Any of the common carriers, such as sterile saline or glucose solution, can be utilized with the drugs provided by the invention. Routes of administration include but are not limited to oral, intracranial ventricular (icv), intrathecal (it), intravenous (iv), parenteral, rectal, topical ophthalmic, subconjunctival, nasal, aural, sublingual (under the tongue) and transdermal. The antioxidant drugs of the invention may be administered intravenously in any conventional medium for intravenous injection such as an aqueous saline medium, or in blood plasma medium. Such medium may also contain conventional pharmaceutical adjunct materials such as, for example, pharmaceutically acceptable salts to adjust the osmotic pressure, lipid carriers such as cyclodextrins, proteins such as serum albumin, hydrophilic agents such as methyl cellulose, detergents, buffers, preservatives and the like. Given the low solubility of many cannabinoids, they may be suspended in sesame oil.

Given the excellent absorption of the compounds of the present invention via an inhaled route, the compounds may also be administered as inhalants, for example in pharmaceutical aerosols utilizing solutions, suspensions, emulsions, powders and semisolid preparations of the type more fully described in *Remington: The Science and Practice of Pharmacy* (19th Edition, 1995) in chapter 95. A particular inhalant form is a metered dose inhalant containing the active ingredient, in a suspension or a dispersing agent (such as sorbitan trioleate, oleyl alcohol, oleic acid, or lecithin, and a propellant such as 12/11 or 12/114).

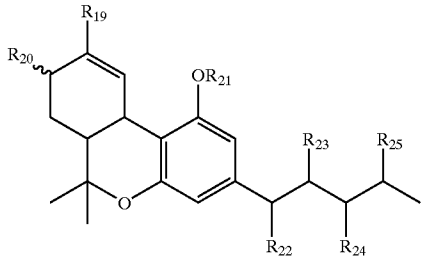
Embodiments of the invention comprising pharmaceutical compositions can be prepared with conventional pharmaceutically acceptable carriers, adjuvants and counterions as would be known to those of skill in the art. The compositions are preferably in the form of a unit dose in solid, semi-solid and liquid dosage forms such as tablets, pills, powders, liquid solutions or suspensions, injectable and infusible solutions, for example a unit dose vial, or a metered dose inhaler. Effective oral human dosage ranges for cannabidiol are contemplated to vary from about 1–40 mg/kg, for example 5–20 mg/kg, and in particular a dose of about 20 mg/kg of body weight.

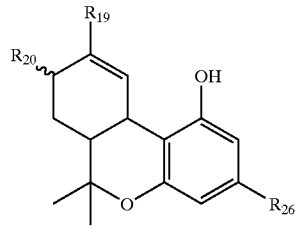
If the antioxidant drugs are to be used in the prevention of cataracts, they may be administered in the form of eye drops formulated in a pharmaceutically inert, biologically acceptable carrier, such as isotonic saline or an ointment. Conventional preservatives, such as benzalkonium chloride, can also be added to the formulation. In ophthalmic ointments, the active ingredient is admixed with a suitable base, such as white petrolatum and mineral oil, along with antimicrobial preservatives. Specific methods of compounding these dosage forms, as well as appropriate pharmaceutical carriers, are known in the art. *Remington: The Science and Practice of Pharmacy,* 19th Ed., Mack Publishing Co. (1995), particularly Part 7.

The compounds of the present invention are ideally administered as soon as a diagnosis is made of an ischemic event, or other oxidative insult. For example, once a myocardial infarction has been confirmed by electrocardiograph, or an elevation in enzymes characteristic of cardiac injury (e.g. CKMB), a therapeutically effective amount of the cannabinoid drug is administered. A dose can also be given following symptoms characteristic of a stroke (motor or sensory abnormalities), or radiographic confirmation of a cerebral infarct in a distribution characteristic of a neurovascular thromboembolic event. The dose can be given by frequent bolus administration, or as a continuous IV dose. In the case of cannabidiol, for example, the drug could be given in a dose of 5 mg/kg active ingredient as a continuous intravenous infusion; or hourly intramuscular injections of that dose.

EXAMPLE 10

The following table lists examples of some dibenzopyran cannabinoids that may be useful as antioxidants in the method of the present invention.

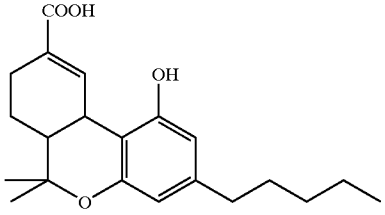




	Compound		R_{19}	R_{20}	R_{21}	R_{22}	R_{23}	R_{24}	R_{25}	R_{26}
H	5	7-OH-Δ^1-THC	CH_2OH	H	H	H	H	H	H	C_5H_{11}
H	6	6α-OH-Δ^1-THC	CH_3	α-OH						
H	7	6β-OH-Δ^1-THC	CH_3	β-OH						
	8	1"-OH-Δ^1-THC	CH_3			OH				
H	9	2"-OH-Δ^1-THC	CH_3				OH			
	10	3"-OH-Δ^1-THC	CH_3					OH		
	11	4"-OH-Δ^1-THC	CH_3						OH	
H	12	6α,7-diOH-Δ^1-THC	CH_2OH	α-OH						
H	13	6v,7-diOH-Δ^1-THC	CH_2OH	β-OH						
	14	1",7-diOH-Δ^1-THC	CH_2OH			OH				
H	15	2",7-diOH-Δ^1-THC	CH_2OH				OH			
H	16	3",7-diOH-Δ^1-THC	CH_2OH					OH		
H	17	4",7-diOH-Δ^1-THC	CH_2OH						OH	
	18	1",6β-diOH-Δ^1-THC	CH_3	β-OH		OH				
	19	1",3"-diOH-Δ^1-THC	CH_3			OH		OH		
	20	1",6α,7-triOH-Δ^1-THC	CH_2OH	α-OH		OH				
H	21	Δ^1-THC-6-one	CH_3	=O						
	22	Epoxyhexahydrocannabinol (EHHC)*	CH_3							
	23	7-oxo-Δ^1-THC	CHO							
H	24	Δ^1-THC-7"-oic acid	COOH							
H	25	Δ^1-THC-3"-oic acid	CH_3							C_2H_4COOH
H	26	1"-OH-Δ^1-THC-7"-oic acid	COOH			OH				
H	27	2"-OH-Δ^1-THC-7"-oic acid	COOH				OH			
H	28	3"-OH-Δ^1-THC-7"-oic acid	COOH					OH		
H	29	4"-OH-Δ^1-THC-7"-oic acid	COOH						OH	
H	30	3",4",5"-trisnor-2"-OH-Δ^1-THC-7-oic acid	COOH							C_2H_4OH
H	31	7-OH-Δ^1-THC-2"-oic acid	CH_2OH							CH_2COOH
H	32	6β-OH-Δ^1-THC-2"-oic acid	CH_3	β-OH						CH_2COOH
H	33	7-OH-Δ^1-THC-3"-oic acid	CH_2OH							C_2H_4COOH
H	34	6β-OH-Δ^1-THC-3"-oic acid	CH_3	β-OH						C_2H_4COOH
H	35	6α-OH-Δ^1-THC-4"-oic acid	CH_3	α-OH						C_3H_6COOH
H	36	2",3"-dehydro-6U-OH-Δ^1-THC-4"-oic acid	CH_3	α-OH						C_3H_4COOH
H	37	Δ^1-THC-1",7-dioic acid	COOH							COOH
H	38	Δ^1-THC-2",7-dioic acid	COOH							CH_2COOH
H	39	Δ^1-THC-3",7-dioic acid	COOH							C_2H_4COOH
H	40	Δ^1-THC-4",7-dioic acid	COOH							C_3H_6COOH
H	41	1",2"-dehydro-Δ^1-THC-3",7-dioic acid	COOH							C_2H_2COOH
H	42	Δ^1-THC-glucuronic acid	CH_3		gluc†					
H	43	Δ^1-THC-7-oic acid glucuronide	COO	gluc†						

*Epoxy group in C-1 and C-2 positions
†Glucuronide
Note: R-group substituents are H if not indicated otherwise.

Chemical structures of some of the dibenzopyran cannabinoids are shown below.



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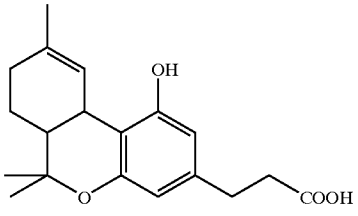

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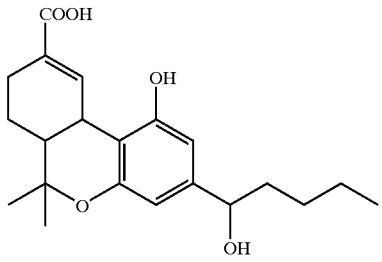

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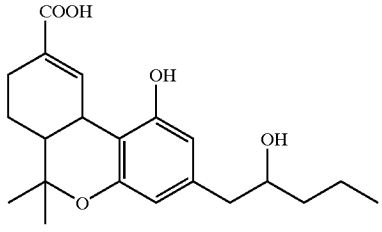

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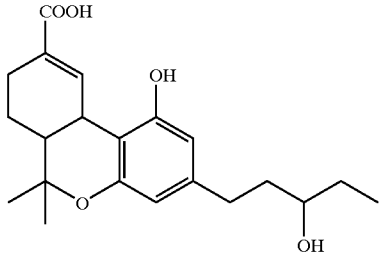

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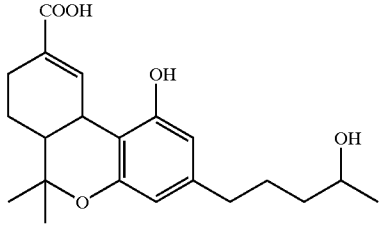

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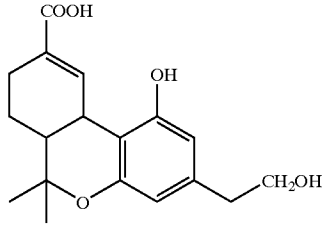

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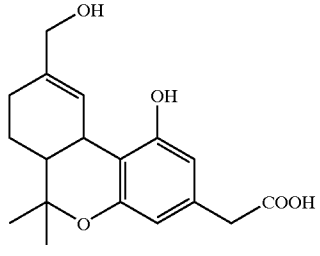

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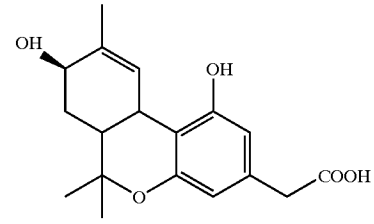

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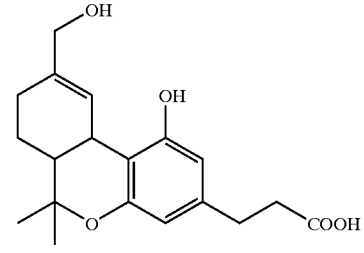

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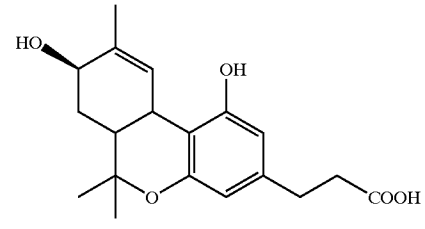

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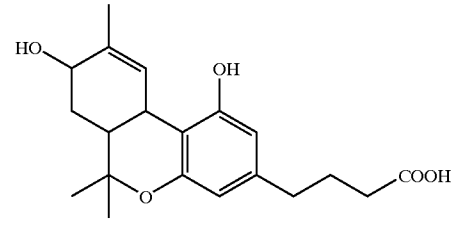

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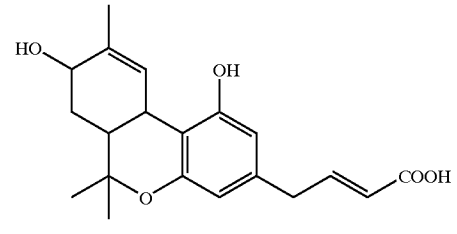

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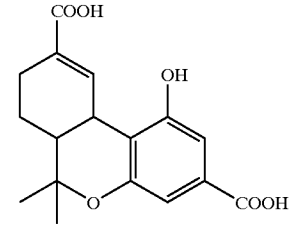

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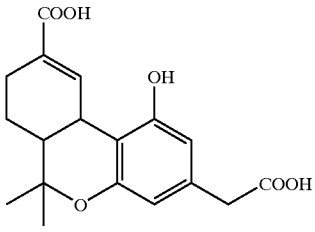

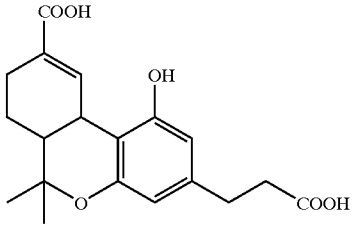

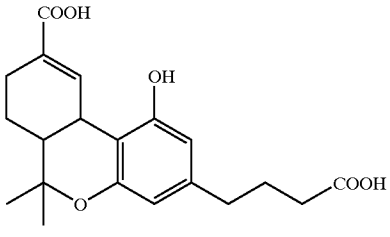

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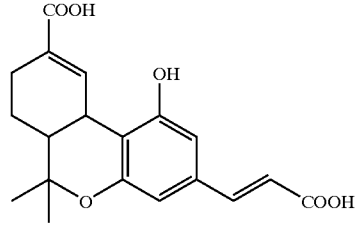
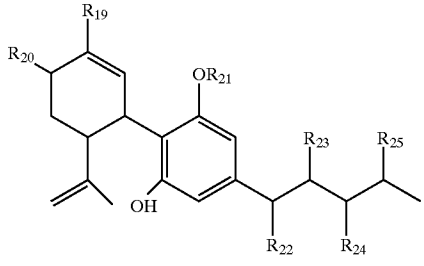
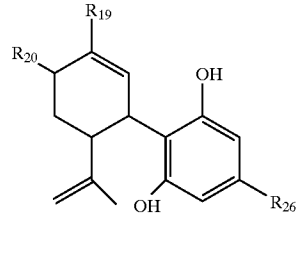


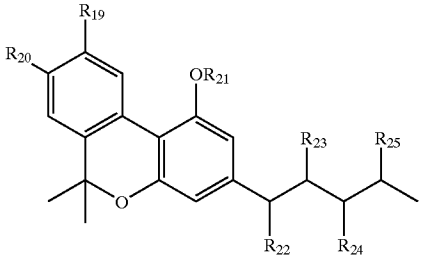
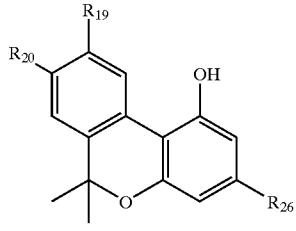
EXAMPLE 11

Examples of Structural Analogs of Cannabidiol

The following table lists examples of some cannabinoids which are structural analogs of cannabidiol and that may be useful as antioxidants in the method of the present invention. A particularly useful example is compound CBD, cannabidiol.

Compound	R_{19}	R_{20}	R_{21}	R_{22}	R_{23}	R_{24}	R_{25}	R_{26}
								
44 CBD	CH_3	H	H	H	H	H	H	C_5H_{11}
45 7-OH—CBD	CH_2OH							
46 6α-	CH_3	α-OH						
47 6β-	CH_3	β-OH						
48 1"-	CH_3			OH				
49 2"-	CH_3				OH			
50 3"-	CH_3					OH		
51 4"-	CH_3						OH	
52 5"-	CH_3							$C_4H_8CH_2OH$
53 6,7-diOH—CBD	CH_2OH	OH						
54 3",7-diOH—CBD	CH_2OH					OH		
55 4",7-diOH—CBD	CH_2OH						OH	
56 CBD-7-oic acid	COOH							
57 CBD-3"-oic acid	CH_3							C_2H_4COOH

-continued

Compound	R_{19}	R_{20}	R_{21}	R_{22}	R_{23}	R_{24}	R_{25}	R_{26}
								
58 CBN	CH_3	H	H	H	H	H	H	C_5H_{11}
59 7-OH—CBN	CH_2OH							
60 1"-OH—CBN	CH_3			OH				
61 2"-OH—CBN	CH_3				OH			
62 3"-OH—CBN	CH_3					OH		
63 4"-OH—CBN	CH_3						OH	
64 5"-OH—CBN	CH_3							$C_4H_8CH_2OH$
65 2"-7-diOH—CBN	CH_2OH				OH			
66 CBN-7-oic acid	COOH							
67 CBN-1"-oic acid	CH_3							COOH
68 CBN-3"-oic acid	CH_3							C_2H_4COOH

Note: R-group substituents are H if not indicated otherwise.

The invention being thus described, variation in the materials and methods for practicing the invention will be apparent to one of ordinary skill in the art. Such variations are to be considered within the scope of the invention, which is set forth in the claims below.

We claim:

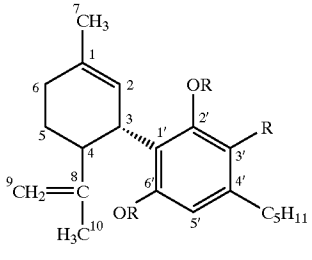
1. A method of treating diseases caused by oxidative stress, comprising administering a therapeutically effective amount of a cannabinoid that has substantially no binding to the NMDA receptor to a subject who has a disease caused by oxidative stress.

2. The method of claim **1**, wherein the cannabinoid is nonpsychoactive.

3. The method of claim **2**, wherein the cannabinoid has a volume of distribution of 10 L/kg or more.

4. The method of claim **1**, wherein the cannabinoid is not an antagonist at the NMDA receptor.

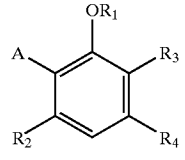
5. The method of claim **1**, wherein the cannabinoid is:



where R is H, substituted or unsubstituted alkyl, carboxyl, alkoxy, aryl, aryloxy, arylalkyl, halo or amino.

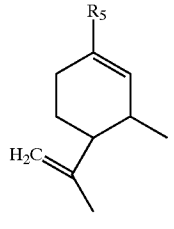
6. The method of claim **5**, wherein R is H, substituted or unsubstituted alkyl, carboxyl or alkoxy.

7. The method of claim **2**, wherein the cannabinoid is:



where

A is cyclohexyl, substituted or unsubstituted aryl, or



but not a pinene;

R_1 is H, substituted or unsubstituted alkyl, or substituted or unsubstituted carboxyl;

R_2 is H, lower substituted or unsubstituted alkyl, or alkoxy;

R_3 is of H, lower substituted or unsubstituted alkyl, or substituted or unsubstituted carboxyl;

R_4 is H, hydroxyl, or lower substituted or unsubstituted alkyl; and

R_5 is H, hydroxyl, or lower substituted or unsubstituted alkyl.

8. The method of claim **7**, wherein

R_1 is lower alkyl, COOH or $COCH_3$;

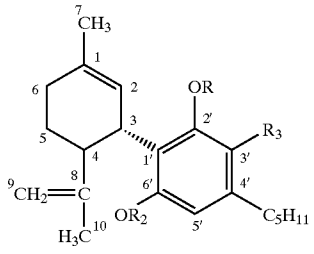
R_2 is unsubstituted C_1–C_5 alkyl, hydroxyl, methoxy or ethoxy;

R_3 is H, unsubstituted C_1–C_3 alkyl, or $COCH_3$;

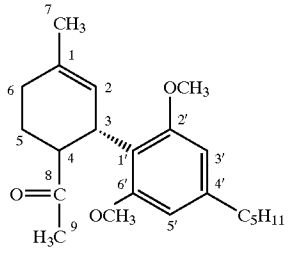
R_4 is hydroxyl, pentyl, heptyl, or diemthylheptyl; and

R_5 is hydroxyl or methyl.

9. The method of claim **1**, wherein the cannabinoid is:

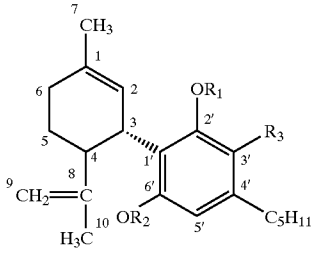


or



where R_1, R_2 and R_3 are independently H, CH_3, or $COCH_3$.

10. The method of claim **9**, wherein the cannabinoid is:



where:

a) R_1=R_2=R_3=H;

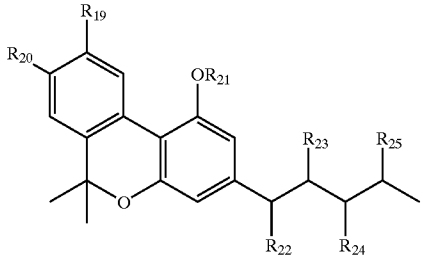
b) R_1=R_3=H, R_2=CH_3;

c) R_1=R_2=CH_3, R_3=H;

d) R_1=R_2=$COCH_3$, R_3=H; or

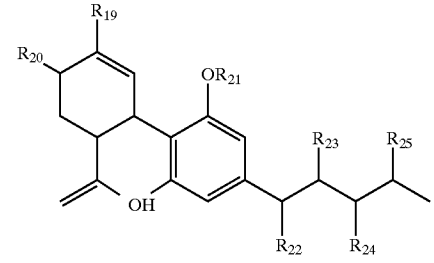
e) R_1=H, R_2=R_3=$COCH_3$.

11. The method of claim **2**, wherein the cannabinoid is:



or

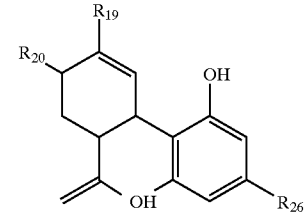
-continued



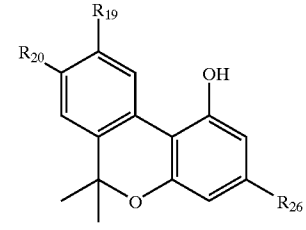
where R_{19} is H, lower alkyl, lower alcohol, or carboxyl; R_{20} is H or OH; and R_{21}–R_{25} are independently H or OH.

12. The method of claim **11**, wherein R_{19} is H, CH_3, CH_2OH, or COOH, and R_{20}–R_{24} are independently H or OH.

13. The method of claim **2**, wherein the cannabinoid is:



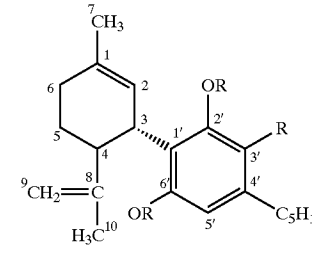
or



where R_{19} and R_{20} are H, and R_{26} is alkyl.

14. The method of claim **10**, wherein the cannabinoid is cannabidiol.

15. A method of treating an ischemic or neurodegenerative disease in the central nervous system of a subject, comprising administering to the subject a therapeutically effective amount of a cannabinoid, where the cannabinoid is



where R is H, substituted or unsubstituted alkyl, carboxyl, alkoxy, aryl, aryloxy, arylalkyl, halo or amino.

16. The method of claim **15**, wherein the cannabinoid is not a psychoactive cannabinoid.

17. The method of claim **15** where the ischemic or neurodegenerative disease is an ischemic infarct, Alzheimer's disease, Parkinson's disease, and human immunodeficiency virus dementia, Down's syndrome, or heart disease.

18. A method of treating a disease with a cannabinoid that has substantially no binding to the NMDA receptor, comprising determining whether the disease is caused by oxi-

dative stress, and if the disease is caused by oxidative stress, administering the cannabinoid in a therapeutically effective antioxidant amount.

19. The method of claim **18**, wherein the cannabinoid has a volume of distribution of at least 1.5 L/kg and substantially no activity at the cannabinoid receptor.

20. The method of claim **19**, wherein the cannabinoid has a volume of distribution of at least 10 L/kg.

21. The method of claim **1**, wherein the cannabinoid selectively inhibits an enzyme activity of 5- and 15-lipoxygenase more than an enzyme activity of 12-lipoxygenase.

22. A method of treating a neurodegenerative or ischemic disease in the central nervous system of a subject, comprising administering to the subject a therapeutically effective amount of a compound selected from any of the compounds of claims **9** through **13**.

23. The method of claim **22** where the compound is cannabidiol.

24. The method of claim **22**, wherein the ischemic or neurodegenerative disease is an ischemic infarct, Alzheimer's disease, Parkinson's disease, and human immunodeficiency virus dementia, Down's syndrome, or heart disease.

25. The method of claim **24** wherein the disease is an ischemic infarct.

26. The method of claim **1**, wherein the cannabinoid is not an antagonist at the AMPA receptor.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,630,507 B1
DATED : October 7, 2003
INVENTOR(S) : Hampson et al.

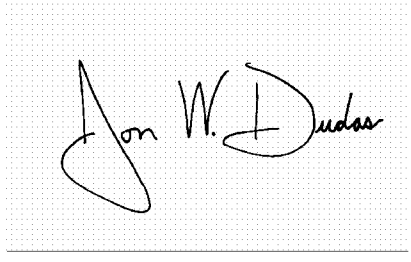
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 13,
Line 23, "feral" should read -- fetal --.

Column 30,
Line 16, reads "R_{20}-R_{24}" should read -- R_{20}-R_{25} --.

Signed and Sealed this

Fifteenth Day of June, 2004



JON W. DUDAS
Acting Director of the United States Patent and Trademark Office

EXHIBIT 5

U.S. Department of Justice

Office of the Deputy Attorney General

The Deputy Attorney General

Washington, D.C. 20530

October 19, 2009

MEMORANDUM FOR SELECTED UNITED STATES ATTORNEYS

FROM: David W. Ogden
Deputy Attorney General

SUBJECT: Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana

This memorandum provides clarification and guidance to federal prosecutors in States that have enacted laws authorizing the medical use of marijuana. These laws vary in their substantive provisions and in the extent of state regulatory oversight, both among the enacting States and among local jurisdictions within those States. Rather than developing different guidelines for every possible variant of state and local law, this memorandum provides uniform guidance to focus federal investigations and prosecutions in these States on core federal enforcement priorities.

The Department of Justice is committed to the enforcement of the Controlled Substances Act in all States. Congress has determined that marijuana is a dangerous drug, and the illegal distribution and sale of marijuana is a serious crime and provides a significant source of revenue to large-scale criminal enterprises, gangs, and cartels. One timely example underscores the importance of our efforts to prosecute significant marijuana traffickers: marijuana distribution in the United States remains the single largest source of revenue for the Mexican cartels.

The Department is also committed to making efficient and rational use of its limited investigative and prosecutorial resources. In general, United States Attorneys are vested with "plenary authority with regard to federal criminal matters" within their districts. USAM 9-2.001. In exercising this authority, United States Attorneys are "invested by statute and delegation from the Attorney General with the broadest discretion in the exercise of such authority." *Id.* This authority should, of course, be exercised consistent with Department priorities and guidance.

The prosecution of significant traffickers of illegal drugs, including marijuana, and the disruption of illegal drug manufacturing and trafficking networks continues to be a core priority in the Department's efforts against narcotics and dangerous drugs, and the Department's investigative and prosecutorial resources should be directed towards these objectives. As a general matter, pursuit of these priorities should not focus federal resources in your States on

individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana. For example, prosecution of individuals with cancer or other serious illnesses who use marijuana as part of a recommended treatment regimen consistent with applicable state law, or those caregivers in clear and unambiguous compliance with existing state law who provide such individuals with marijuana, is unlikely to be an efficient use of limited federal resources. On the other hand, prosecution of commercial enterprises that unlawfully market and sell marijuana for profit continues to be an enforcement priority of the Department. To be sure, claims of compliance with state or local law may mask operations inconsistent with the terms, conditions, or purposes of those laws, and federal law enforcement should not be deterred by such assertions when otherwise pursuing the Department's core enforcement priorities.

Typically, when any of the following characteristics is present, the conduct will not be in clear and unambiguous compliance with applicable state law and may indicate illegal drug trafficking activity of potential federal interest:

- unlawful possession or unlawful use of firearms;
- violence;
- sales to minors;
- financial and marketing activities inconsistent with the terms, conditions, or purposes of state law, including evidence of money laundering activity and/or financial gains or excessive amounts of cash inconsistent with purported compliance with state or local law;
- amounts of marijuana inconsistent with purported compliance with state or local law;
- illegal possession or sale of other controlled substances; or
- ties to other criminal enterprises.

Of course, no State can authorize violations of federal law, and the list of factors above is not intended to describe exhaustively when a federal prosecution may be warranted. Accordingly, in prosecutions under the Controlled Substances Act, federal prosecutors are not expected to charge, prove, or otherwise establish any state law violations. Indeed, this memorandum does not alter in any way the Department's authority to enforce federal law, including laws prohibiting the manufacture, production, distribution, possession, or use of marijuana on federal property. This guidance regarding resource allocation does not "legalize" marijuana or provide a legal defense to a violation of federal law, nor is it intended to create any privileges, benefits, or rights, substantive or procedural, enforceable by any individual, party or witness in any administrative, civil, or criminal matter. Nor does clear and unambiguous compliance with state law or the absence of one or all of the above factors create a legal defense to a violation of the Controlled Substances Act. Rather, this memorandum is intended solely as a guide to the exercise of investigative and prosecutorial discretion.

Finally, nothing herein precludes investigation or prosecution where there is a reasonable basis to believe that compliance with state law is being invoked as a pretext for the production or distribution of marijuana for purposes not authorized by state law. Nor does this guidance preclude investigation or prosecution, even when there is clear and unambiguous compliance with existing state law, in particular circumstances where investigation or prosecution otherwise serves important federal interests.

Your offices should continue to review marijuana cases for prosecution on a case-by-case basis, consistent with the guidance on resource allocation and federal priorities set forth herein, the consideration of requests for federal assistance from state and local law enforcement authorities, and the Principles of Federal Prosecution.

cc: All United States Attorneys

Lanny A. Breuer
Assistant Attorney General
Criminal Division

B. Todd Jones
United States Attorney
District of Minnesota
Chair, Attorney General's Advisory Committee

Michele M. Leonhart
Acting Administrator
Drug Enforcement Administration

H. Marshall Jarrett
Director
Executive Office for United States Attorneys

Kevin L. Perkins
Assistant Director
Criminal Investigative Division
Federal Bureau of Investigation

EXHIBIT 6

USDA

JUL 10 2012

United States Department of Agriculture

Food and Nutrition Service

3101 Park Center Drive

Alexandria, VA 22302-1500

SUBJECT: Medical Deductions—Medical Marijuana and Other Illegal Substances

TO: All Regional Directors
Supplemental Nutrition Assistance Program

This memorandum is to reaffirm Food and Nutrition Service (FNS) policy regarding the Supplemental Nutrition Assistance Program (SNAP) medical deduction and medicinal marijuana. Due to the increase in the number of States with laws that permit the use of marijuana for medicinal purposes, FNS is now reaffirming its long standing policy that a household may not utilize the SNAP medical deduction for the cost of any substance considered illegal under Federal law.

Section 5(e)(5) of the Food and Nutrition Act of 2008 (FNA), 7 U.S.C. § 2011 et seq., allows households with elderly or disabled members to deduct "allowable medical expenses" from their income for the purposes of SNAP eligibility. This statutory provision is designed to allow elderly or disabled households, who often have significant medical costs, to receive food help. Section 3(c)(3) of the FNA defines "allowable medical expenses" to include "expenditures for prescription drugs when prescribed by a licensed practitioner authorized under State law." There is no provision in the FNA that allows households to deduct the cost of substances considered illegal under Federal law.

Currently eighteen States have state statutory provisions that allow doctors to prescribe medicinal marijuana to patients in limited circumstances. It has come to FNS' attention that some State agencies are allowing elderly or disabled households to deduct the cost of medicinal marijuana from their income for SNAP purposes. Under the Controlled Substances Act, 21 U.S.C. § 801 et seq., marijuana is a Schedule I controlled substance that has no currently accepted medical use and cannot be prescribed for medicinal purposes. 21 U.S.C. § 812(b)(1), (c). SNAP is a Federal program and must conform to Federal law regarding illegal substances. Therefore, marijuana and other Schedule I controlled substances are not "allowable medical expenses" under Federal law.

States that currently allow for the deduction of medical marijuana must cease this practice immediately and make any necessary corrections to their State policy manuals and instructions. Cases that cannot be readily identified must be corrected at the time of recertification or periodic report, whichever is sooner. States that are not in compliance may face penalties for any overissuance of SNAP benefits.

Should you have any questions about this policy, please contact Angela Kline at Angela.Kline@fns.usda.gov.

for

Lizbeth Silbermann
Director
Program Development Division

EXHIBIT 7

U.S. Department of Justice

Office of the Deputy Attorney General

The Deputy Attorney General

Washington, D.C. 20530

August 29, 2013

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS

FROM: James M. Cole
Deputy Attorney General

SUBJECT: Guidance Regarding Marijuana Enforcement

In October 2009 and June 2011, the Department issued guidance to federal prosecutors concerning marijuana enforcement under the Controlled Substances Act (CSA). This memorandum updates that guidance in light of state ballot initiatives that legalize under state law the possession of small amounts of marijuana and provide for the regulation of marijuana production, processing, and sale. The guidance set forth herein applies to all federal enforcement activity, including civil enforcement and criminal investigations and prosecutions, concerning marijuana in all states.

As the Department noted in its previous guidance, Congress has determined that marijuana is a dangerous drug and that the illegal distribution and sale of marijuana is a serious crime that provides a significant source of revenue to large-scale criminal enterprises, gangs, and cartels. The Department of Justice is committed to enforcement of the CSA consistent with those determinations. The Department is also committed to using its limited investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational way. In furtherance of those objectives, as several states enacted laws relating to the use of marijuana for medical purposes, the Department in recent years has focused its efforts on certain enforcement priorities that are particularly important to the federal government:

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;

- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
- Preventing marijuana possession or use on federal property.

These priorities will continue to guide the Department's enforcement of the CSA against marijuana-related conduct. Thus, this memorandum serves as guidance to Department attorneys and law enforcement to focus their enforcement resources and efforts, including prosecution, on persons or organizations whose conduct interferes with any one or more of these priorities, regardless of state law.[1]

Outside of these enforcement priorities, the federal government has traditionally relied on states and local law enforcement agencies to address marijuana activity through enforcement of their own narcotics laws. For example, the Department of Justice has not historically devoted resources to prosecuting individuals whose conduct is limited to possession of small amounts of marijuana for personal use on private property. Instead, the Department has left such lower-level or localized activity to state and local authorities and has stepped in to enforce the CSA only when the use, possession, cultivation, or distribution of marijuana has threatened to cause one of the harms identified above.

The enactment of state laws that endeavor to authorize marijuana production, distribution, and possession by establishing a regulatory scheme for these purposes affects this traditional joint federal-state approach to narcotics enforcement. The Department's guidance in this memorandum rests on its expectation that states and local governments that have enacted laws authorizing marijuana-related conduct will implement strong and effective regulatory and enforcement systems that will address the threat those state laws could pose to public safety, public health, and other law enforcement interests. A system adequate to that task must not only contain robust controls and procedures on paper; it must also be effective in practice. Jurisdictions that have implemented systems that provide for regulation of marijuana activity

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[1] These enforcement priorities are listed in general terms; each encompasses a variety of conduct that may merit civil or criminal enforcement of the CSA. By way of example only, the Department's interest in preventing the distribution of marijuana to minors would call for enforcement not just when an individual or entity sells or transfers marijuana to a minor, but also when marijuana trafficking takes place near an area associated with minors; when marijuana or marijuana-infused products are marketed in a manner to appeal to minors; or when marijuana is being diverted, directly or indirectly, and purposefully or otherwise, to minors.

must provide the necessary resources and demonstrate the willingness to enforce their laws and regulations in a manner that ensures they do not undermine federal enforcement priorities.

In jurisdictions that have enacted laws legalizing marijuana in some form and that have also implemented strong and effective regulatory and enforcement systems to control the cultivation, distribution, sale, and possession of marijuana, conduct in compliance with those laws and regulations is less likely to threaten the federal priorities set forth above. Indeed, a robust system may affirmatively address those priorities by, for example, implementing effective measures to prevent diversion of marijuana outside of the regulated system and to other states, prohibiting access to marijuana by minors, and replacing an illicit marijuana trade that funds criminal enterprises with a tightly regulated market in which revenues are tracked and accounted for. In those circumstances, consistent with the traditional allocation of federal-state efforts in this area, enforcement of state law by state and local law enforcement and regulatory bodies should remain the primary means of addressing marijuana-related activity. If state enforcement efforts are not sufficiently robust to protect against the harms set forth above, the federal government may seek to challenge the regulatory structure itself in addition to continuing to bring individual enforcement actions, including criminal prosecutions, focused on those harms.

The Department's previous memoranda specifically addressed the exercise of prosecutorial discretion in states with laws authorizing marijuana cultivation and distribution for medical use. In those contexts, the Department advised that it likely was not an efficient use of federal resources to focus enforcement efforts on seriously ill individuals, or on their individual caregivers. In doing so, the previous guidance drew a distinction between the seriously ill and their caregivers, on the one hand, and large-scale, for-profit commercial enterprises, on the other, and advised that the latter continued to be appropriate targets for federal enforcement and prosecution. In drawing this distinction, the Department relied on the common-sense judgment that the size of a marijuana operation was a reasonable proxy for assessing whether marijuana trafficking implicates the federal enforcement priorities set forth above.

As explained above, however, both the existence of a strong and effective state regulatory system, and an operation's compliance with such a system, may allay the threat that an operation's size poses to federal enforcement interests. Accordingly, in exercising prosecutorial discretion, prosecutors should not consider the size or commercial nature of a marijuana operation alone as a proxy for assessing whether marijuana trafficking implicates the Department's enforcement priorities listed above. Rather, prosecutors should continue to review marijuana cases on a case-by-case basis and weigh all available information and evidence, including, but not limited to, whether the operation is demonstrably in compliance with a strong and effective state regulatory system. A marijuana operation's large scale or for-profit nature may be a relevant consideration for assessing the extent to which it undermines a particular federal enforcement priority. The primary question in all cases – and in all jurisdictions – should be whether the conduct at issue implicates one or more of the enforcement priorities listed above.

As with the Department's previous statements on this subject, this memorandum is intended solely as a guide to the exercise of investigative and prosecutorial discretion. This memorandum does not alter in any way the Department's authority to enforce federal law, including federal laws relating to marijuana, regardless of state law. Neither the guidance herein nor any state or local law provides a legal defense to a violation of federal law, including any civil or criminal violation of the CSA. Even in jurisdictions with strong and effective regulatory systems, evidence that particular conduct threatens federal priorities will subject that person or entity to federal enforcement action, based on the circumstances. This memorandum is not intended to, does not, and may not be relied upon to create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal. It applies prospectively to the exercise of prosecutorial discretion in future cases and does not provide defendants or subjects of enforcement action with a basis for reconsideration of any pending civil action or criminal prosecution. Finally, nothing herein precludes investigation or prosecution, even in the absence of any one of the factors listed above, in particular circumstances where investigation and prosecution otherwise serves an important federal interest.

cc: Mythili Raman
Acting Assistant Attorney General, Criminal Division

Loretta E. Lynch
United States Attorney
Eastern District of New York
Chair, Attorney General's Advisory Committee

Michele M. Leonhart
Administrator
Drug Enforcement Administration

H. Marshall Jarrett
Director
Executive Office for United States Attorneys

Ronald T. Hosko
Assistant Director
Criminal Investigative Division
Federal Bureau of Investigation

EXHIBIT 8

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington DC 20201

DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS

As a result of the consequences of the opioid crisis affecting our Nation, on this date and after consultation with public health officials as necessary, I, Eric D. Hargan, Acting Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby determine that a public health emergency exists nationwide.

10/26/2017
Date

Eric D. Hargan
Acting Secretary

EXHIBIT 9

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1315
Transmittal Sheet
July 28, 2023

ACCESS TO VHA CLINICAL PROGRAMS FOR VETERANS PARTICIPATING IN STATE-APPROVED MARIJUANA PROGRAMS

1. SUMMARY OF MAJOR CHANGES: This directive:

a. Updates roles, titles and responsibilities for the Assistant Under Secretary for Health for Patient Care Services and Assistant Under Secretary for Health for Operations and adds responsibilities for the Executive Director, Health Solutions and Department of Veterans Affairs (VA) health care provider (see paragraph 2).

b. Removes responsibilities for the Chief Consultant, Population Health Services.

c. Clarifies definition of marijuana to account for updates in 21 U.S.C. § 802(16) as a result of section 12619 of the Agriculture Improvement Act of 2018 (P.L. 114-334).

2. RELATED ISSUES: None.

3. POLICY OWNER: Health Solutions (12POP2) within the Office of Patient Care Services (12PCS) is responsible for the content of this directive. Questions may be referred to the Executive Director, Health Solutions at Health.Solutions@va.gov.

4. RESCISSIONS: VHA Directive 1315, Access to VHA Clinical Programs for Veterans Participating in State-Approved Marijuana Programs, dated December 8, 2017, is rescinded.

5. RECERTIFICATION: This Veterans Health Administration (VHA) directive is scheduled for recertification on or before the last working day of July 2028. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

6. IMPLEMENTATION SCHEDULE: This directive is effective upon publication.

BY DIRECTION OF THE OFFICE OF
THE UNDER SECRETARY FOR HEALTH:

/s/ M. Christopher Saslo
DNS, ARNP-BC, FAANP
Assistant Under Secretary for Health
for Patient Care Services/CNO

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

DISTRIBUTION: Emailed to the VHA Publications Distribution List on July 31, 2023.

CONTENTS

ACCESS TO VHA CLINICAL PROGRAMS FOR VETERANS PARTICIPATING IN STATE-APPROVED MARIJUANA PROGRAMS

ACCESS TO VHA CLINICAL PROGRAMS FOR VETERANS PARTICIPATING IN STATE-APPROVED MARIJUANA PROGRAMS

1. POLICY

It is Veterans Health Administration (VHA) policy that Department of Veteran Affairs (VA) health care providers discuss relevant clinical information regarding marijuana use with Veterans who request information about marijuana or report marijuana use and document this information in the Veteran's electronic health record (EHR). ***NOTE:*** *Clinical treatment decisions based on marijuana use must be made on a case-by-case basis based on concerns regarding Veteran health and safety. Veterans must not be denied VHA services solely because they are participating in a State-approved marijuana program or because they acknowledge use of marijuana. To comply with Federal laws such as the Controlled Substances Act (21 U.S.C. § 801 et. seq.), VA health care providers are prohibited from recommending, making referrals to, completing forms or registering Veterans for participation in a State-approved marijuana program.* **AUTHORITY:** 38 U.S.C. § 7301(b).

2. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Patient Care Services.** The Assistant Under Secretary for Health for Patient Care Services is responsible for supporting Health Solutions with implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

(4) Ensuring that all VISN Directors and VA medical facility Directors are aware that VA health care providers may assess Veteran use of marijuana but that they are prohibited from recommending, making referrals to, completing forms or registering Veterans for participation in State-approved marijuana programs.

d. **Executive Director, Health Solutions.** The Executive Director, Health Solutions is responsible for providing oversight for the VISN and VA medical facility compliance with this directive and ensuring corrective action is taken when non-compliance is identified.

e. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

(2) Communicating to VA medical facility Directors that VA health care providers may assess Veteran use of marijuana but are prohibited from recommending, making referrals to, completing forms or registering Veterans for participation in State-approved marijuana programs.

f. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring overall VA medical facility compliance with this directive and that appropriate corrective action is taken if non-compliance is identified.

(2) Ensuring VA health care providers discuss relevant clinical information regarding marijuana with each Veteran who requests information about marijuana or reports marijuana use and document this discussion in the Veteran's EHR.

(3) Ensuring VA medical facility staff are aware of the prohibition on recommending, making referrals to, completing forms or registering Veterans for participation in State-approved marijuana programs.

(4) Ensuring that if a Veteran presents an authorization for marijuana to a VA health care provider, the Veteran is made aware that the VA medical facility will not provide marijuana to the Veteran, including payment or reimbursement for marijuana to be provided to the Veteran.

(5) Ensuring VA medical facility staff are aware, and inform VA patients, that possession of marijuana while on VA medical facility property, including that obtained from a State-approved marijuana program, is a violation of 38 C.F.R. § 1.218(a)(7) and subject to prosecution under the Controlled Substances Act, 21 U.S.C. § 844.

(6) Ensuring that if a Veteran reports marijuana use or participation in a State-approved marijuana program to a member of the clinical staff, that information is documented in the Veteran's EHR and considered in the development or modification of the treatment plan on a case-by-case basis based on concerns regarding Veteran health and safety.

g. **VA Health Care Provider.** The VA health care provider is responsible for, if a Veteran reports marijuana use or participation in a State-approved marijuana program, discussing relevant clinical information regarding marijuana with the Veteran and documenting this information in the Veteran's EHR. This includes discussing how their use of marijuana may relate to other clinical activities such as how marijuana may interact with other medications the Veteran is taking, or how the use of marijuana may impact other aspects of care such as pain management and

treatment of mental health disorders, including but not limited to post-traumatic stress disorder, or substance use disorder treatment.

3. TRAINING

There are no formal training requirements associated with this directive. A VA factsheet is available at: https://www.publichealth.va.gov/marijuana.asp.

4. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

5. DEFINITIONS

a. **Controlled Substances Act.** The Controlled Substances Act (21 U.S.C. § 801 et seq.) places all substances which are in some manner regulated under existing Federal law into one of five schedules based on their medical use, potential for abuse and safety or dependency liability. Schedule I includes drugs or other substances with a high potential for abuse, without a currently accepted medical use in the United States and lacking accepted safety for use under medical supervision. Marijuana is classified as a Schedule I drug.

b. **Marijuana.** For purposes of this directive, marijuana is all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or resin. This term does not include:

(1) Hemp, defined as the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3% on a dry weight basis.

(2) The mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil or cake or the sterilized seed of such plant which is incapable of germination.

6. REFERENCES

a. 7 U.S.C. § 1639o.

b. 21 U.S.C. §§ 801 et seq.

c. 38 C.F.R. § 1.218(a)(7).

d. VA Public Health, VA and Marijuana – What Veterans Need to Know. https://www.publichealth.va.gov/marijuana.asp.

EXHIBIT 10

RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CHS. 1141 AND 1151]

Medical Marijuana; General Provisions; Growers/Processors; Amended Temporary Regulations

[48 Pa.B. 2767]
[Saturday, May 12, 2018]

The Department of Health (Department) is publishing amended temporary regulations in Chapters 1141 and 1151 (relating to general provisions—temporary regulations; and growers/processors—temporary regulations) to read as set forth in Annex A. These amended temporary regulations are published under the Medical Marijuana Act (act) (35 P.S. §§ 10231.101—10231.2110). Section 1107 of the act (35 P.S. § 10231.1107) specifically provides that, to facilitate the prompt implementation of the act, the Department may promulgate temporary regulations that are not subject to sections 201—205 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201—1205), known as the Commonwealth Documents Law, the Regulatory Review Act (71 P.S. §§ 745.1—745.14) and sections 204(b) and 301(10) of the Commonwealth Attorneys Act (71 P.S. §§ 732-204(b) and 732-301(10)).

To implement the Medical Marijuana Program, the Department periodically published temporary regulations regarding various sections of the act. Chapter 1141 sets forth the general requirements for the Medical Marijuana Program. Chapter 1151 sets forth the requirements for an entity to become permitted and operate as a grower/processor under the act.

The Department is amending the existing temporary regulations in Chapters 1141 and 1151 for the sake of consistency, and to take into account the need for changes that have arisen as each new set of temporary regulations has been implemented by the Department. Under section 1202 of the act (35 P.S. § 10231.1202), the Department is also amending the existing temporary regulations to effectuate the recommendations made by the Medical Marijuana Advisory Board (Board). After consideration of the Board's report, the Secretary of Health decided to implement the Board's recommendations through the promulgation of temporary regulations.

These amended temporary regulations in Chapters 1141 and 1151 will become effective May 17, 2018, and will expire on May 12, 2020.

Interested persons are invited to submit written comments, suggestions or objections regarding these amended temporary regulations to John J. Collins, Office of Medical Marijuana, Department of Health, Room 628, Health and Welfare Building, 625 Forster Street, Harrisburg, PA 17120, (717) 547-3047, RA-DHMedMarijuana@pa.gov.

Persons with a disability who wish to submit comments, suggestions or objections regarding these amended temporary regulations or who require an alternative format of these amended temporary regulations (for example, large print, audiotape, Braille) may do so by using the previous

Permit—An authorization issued by the Department to an applicant to conduct activities authorized under the act.

Permittee—A person who has been issued an authorization to operate as a medical marijuana organization under the act and this part.

Person—A natural person, corporation, foundation, organization, business trust, estate, limited liability company, licensed corporation, trust, partnership, limited liability partnership, association or other form of legal business entity.

Practitioner—A physician who is registered with the Department under section 401 of the act (35 P.S. § 10231.401).

Principal—An officer, director or person who directly or beneficially owns securities of an applicant or permittee, or a person who has a controlling interest in an applicant or permittee or who has the ability to elect the majority of the board of directors of an applicant or permittee or otherwise control an applicant or permittee, other than a financial institution.

Publicly traded company—A person other than an individual who:

(i) Has a class or series of securities registered under the Securities Exchange Act of 1934 (15 U.S.C.A. §§ 78a—78pp) or on a foreign stock exchange determined by the Department to have similar listing and reporting requirements to exchanges that are regulated under the Securities Exchange Act of 1934.

(ii) Is a registered management company under the Investment Company Act of 1940 (15 U.S.C.A. §§ 80a-1—80a-64).

(iii) Is subject to the reporting obligations imposed by section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C.A. § 78o(d)) by reason of having filed a registration statement which has become effective under the Securities Act of 1933 (15 U.S.C.A. §§ 77a—77aa).

Security—The term as defined in section 102(t) of the Pennsylvania Securities Act of 1972 (70 P.S. § 1-102(t)).

Serious medical condition—Any of the following conditions:

(i) Cancer, including remission therapy.

(ii) Positive status for Human Immunodeficiency Virus or Acquired Immune Deficiency Syndrome.

(iii) Amyotrophic lateral sclerosis.

(iv) Parkinson's disease.

(v) Multiple sclerosis.

(vi) Damage to the nervous tissue of the central nervous system (brain-spinal cord) with objective neurological indication of intractable spasticity, and other associated neuropathies.

(vii) Epilepsy.

(viii) Inflammatory bowel disease.

(ix) Neuropathies.

(x) Huntington's disease.

(xi) Crohn's disease.

(xii) Post-traumatic stress disorder.

(xiii) Intractable seizures.

(xiv) Glaucoma.

(xv) Sickle cell anemia.

(xvi) Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain.

(xvii) Autism.

(xviii) Neurodegenerative diseases.

(ixx) Terminal illness.

(xx) Dyskinetic and spastic movement disorders.

(xxi) Opioid use disorder for which conventional therapeutic interventions are contraindicated or ineffective, or for which adjunctive therapy is indicated in combination with primary therapeutic interventions.

Service-disabled—The term as defined in 51 Pa.C.S. § 9601 (relating to definitions).

Service-disabled veteran-owned small business—The term as defined in 51 Pa.C.S. § 9601.

Site—The total area contained within the property line boundaries in which a facility is operated by a medical marijuana organization.

Spent hydroponic nutrient solution—Hydroponic nutrient solution that has been used and can no longer serve the purpose for which it was produced.

THC—Tetrahydrocannabinol.

Terminal illness—A condition or disease for which the medical prognosis of life expectancy is approximately 1 year or less if the condition or disease runs its normal course.

Third-party certifying organization—The term as defined in 74 Pa.C.S. § 303(b).

Transport vehicle—A vehicle that meets the requirements of the act and is used to transport seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products between medical marijuana organizations or between medical marijuana organizations and an approved laboratory.

Unit—The weight or volume of total usable medical marijuana products, calculated in metric units.

Vaporization—The generation of medical marijuana products in the form of vapor for medicinal inhalation.

Veteran—The term as defined in 51 Pa.C.S. § 9601.

EXHIBIT 11

Housing Authority of Indiana County

H·A·I·C

June 13, 2018

Ms. Mary Cease

Dear Ms. Cease:

Your application for admission into our Section 8 program has been processed. We are sorry to inform you that your request for admission has been denied for the following reason:

- **We must deny program participation as marijuana is still considered to be an illegal substance by the Federal government and costs associated with marijuana medical treatments cannot be considered in calculation of adjusted income.**

If you disagree with our conclusion, you have the right to an informal conference, which you may obtain by writing to the Housing Authority at 104 Philadelphia Street, Indiana, PA 15701, within ten (10) days from the date of this letter, asking for a conference. You may have an attorney or any other interested party represent you at the informal conference.

If you or someone in your household is a person with disabilities and require a specific reasonable accommodation in order to fully utilize our program and services, please notify our office.

If any adult member of the household should require an interpreter due to a language barrier, please make known those requirements to the Housing Authority.

Sincerely,

Holly M. Hall, PHM
Section 8 Coordinator

HMH

EXHIBIT 12

Housing Authority of Indiana County

H·A·I·C

March 29, 2023

Sara Bloch

Dear Sara:

Your application for admission into our Section 8 program has been processed. We are sorry to inform you that your request for admission has been denied for the following reason:

Your application included a letter from Rebecca Lang, CCMA, which indicated that you currently use MMJ (a common acronym for medical marijuana) for chronic pain. Pursuant to the Housing Authority's Rules and Regulations and guidelines promulgated by the United States Department of Housing and Urban Development, a new applicant is prohibited admission into the Section 8 program if the applicant is currently a user of a Schedule 1 controlled substance under federal law.

If you disagree with our conclusion, you have the right to an informal conference, which you may obtain by writing to the Housing Authority at 104 Philadelphia Street, Indiana, PA 15701, within ten calendar (10) days from the date of this letter, asking for a conference. You may have an attorney or any other interested party represent you at the informal conference.

If you or someone in your household is a person with disabilities and require a specific reasonable accommodation in order to fully utilize our program and services, please notify our office.

If any adult member of the household should require an interpreter due to a language barrier, please make known those requirements to the Housing Authority.

Sincerely,

Holly M. Hall, PHM
Section 8 Coordinator

HMH

Section 8 W/L denial

104 Philadelphia Street, Indiana, PA 15701
Telephone & TDD: 724-463-4730 Fax: 724-463-4743

EXHIBIT 13

pennsylvania
DEPARTMENT OF LABOR & INDUSTRY
OFFICE OF VOCATIONAL REHABILITATION

ELIGIBILITY AND PRIORITY CATEGORY NOTIFICATION

MS. SARA J BLOCH

04/15/2022

Dear Sara Bloch:

Based on the information you provided during our initial interview and other documentation received, you have been determined eligible to receive services from the Office of Vocational Rehabilitation (OVR).

When OVR does not have sufficient funds to provide services to all eligible individuals with disabilities, OVR is required by Federal law to provide services according to an Order of Selection. An Order of Selection gives priority to individuals with the most significant disabilities. The significance of disability is determined through an assessment of functional limitations related to employment and the need for multiple services over an extended period of time.

OVR's Order of Selection places all eligible individuals into one of three priority categories as follows:

- Individuals with Most Significant Disabilities (MSD)
- Individuals with Significant Disabilities (SD)
- Individuals with Non-Significant Disabilities (NSD)

You have been placed into the following Order of Selection Category: Significant Disability (SD)

Reich
B Cheeks -

pennsylvania
DEPARTMENT OF LABOR & INDUSTRY
OFFICE OF VOCATIONAL REHABILITATION

ELIGIBILITY AND PRIORITY CATEGORY NOTIFICATION

Please contact me at 412-916-8920 or afu@pa.gov to discuss next steps.

Sincerely,

Albert Fu/dd

Albert Fu
Vocational Rehabilitation Counselor

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
PITTSBURGH DIVISION

Sara Bloch, Mary Cease, and the Housing Authority of Indiana County, *Plaintiffs*, v. U.S. Department of Housing and Urban Development and Marcia Fudge, in her official capacity as Secretary, U.S. Department of Housing and Urban Development, *Defendants*.	:	Case No. 2:23-cv-01660-NR

CERTIFICATE OF SERVICE

I hereby certify that I served a true and correct copy of Plaintiff's First Amended Complaint upon the person(s) and in the manner indicated below:

VIA ECF

Cynthia Liao, Esq.
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L St. NW
Washington, DC 20005
Counsel for Defendants

/s/ Aaron D. Rosengarten
Aaron D. Rosengarten

Dated: January 10, 2024